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(54) **MINIMALLY INVASIVE REPAIR OF A VALVE LEAFLET IN A BEATING HEART**

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(58) **Field of Classification Search**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,751,908	A	6/1956	Wallace
3,667,474	A	6/1972	Lapkin et al.
3,842,840	A	10/1974	Schweizer
4,258,716	A	3/1981	Sutherland

(Continued)

FOREIGN PATENT DOCUMENTS

EP	1 039 851	B1	7/2005
EP	1 637 091	A2	3/2006

(Continued)

OTHER PUBLICATIONS

Port Access System for Mitral Valve Repair Proves Its Value in Study; MedGadget Jul. 9, 2009; available at: http://www.medgadget.com/archives/2009/07/port access system for mitral valve repair proves its value in study.html (5 pages).

Interactive Cardio Vascular and Thoracic Surgery; Abstracts: Supplemental 3 to vol. 7 (Sep. 2008). 52 pages.

International Search Report for International Application No. PCT/US/2008/080560 (Aug. 25, 2009) 3 pages.

International Search Report for International Application No. PCT/US/2008/080560 (Aug. 28, 2009) (2 pages).

U.S. Appl. No. 12/709,220, filed Feb. 19, 2010; Giovanni Speziali.

File History for U.S. Appl. No. 12/254,807; Published Apr. 23, 2009; John Zentgraf.

File History for U.S. Appl. No. 11/813,695; Published Aug. 7, 2008; Giovanni Speziali.

(Continued)

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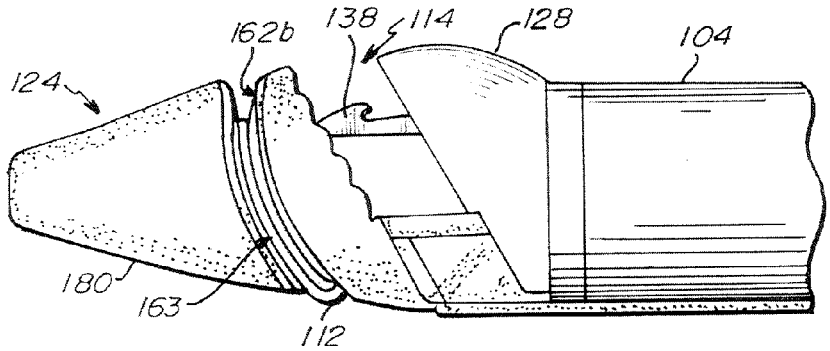
(57) **ABSTRACT**

A valve repair device with a replaceable suture cartridge for repair of a valve leaflet in a beating heart of a patient includes a valve repair device and a replaceable suture cartridge. The valve repair device can include a handle with an actuator, a capture assembly including one portion of a jaw assembly adapted to grasp the leaflet and a needle head for penetrating the leaflet. The replaceable suture cartridge can include a secondary shaft including a second portion of the jaw assembly integrally couplable to the capture assembly and a channel within which a suture is carried.

15 Claims, 27 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

4,351,345	A		9/1982	Carney
4,935,027	A	*	6/1990	Yoon 606/146
4,957,498	A		9/1990	Caspari et al.
4,960,424	A		10/1990	Grooters
4,972,874	A		11/1990	Jackson
5,059,201	A		10/1991	Asnis
5,211,650	A		5/1993	Noda
5,297,536	A		3/1994	Wilk
5,304,185	A		4/1994	Taylor
5,312,423	A		5/1994	Rosenbluth et al.
5,336,229	A	*	8/1994	Noda 606/144
5,336,231	A	*	8/1994	Adair 606/148
5,383,877	A		1/1995	Clarke
5,431,666	A	*	7/1995	Sauer et al. 606/139
5,452,733	A		9/1995	Sterman et al.
5,474,519	A		12/1995	Bloomer
5,547,455	A		8/1996	McKenna et al.
5,571,215	A		11/1996	Sterman et al.
5,601,578	A		2/1997	Murphy
5,626,607	A		5/1997	Malecki
5,653,716	A		8/1997	Malo et al.
5,665,100	A		9/1997	Yoon
5,667,472	A		9/1997	Finn et al.
5,667,473	A		9/1997	Finn et al.
5,667,478	A		9/1997	McFarlin et al.
5,693,091	A		12/1997	Larson, Jr. et al.
5,728,113	A		3/1998	Sherts
5,762,458	A		6/1998	Wang
5,762,613	A		6/1998	Sutton et al.
5,772,597	A		6/1998	Goldberger et al.
5,772,672	A		6/1998	Toy et al.
5,785,658	A		7/1998	Benaron et al.
5,797,960	A		8/1998	Stevens et al.
5,830,231	A	*	11/1998	Geiges, Jr. 606/205
5,839,639	A		11/1998	Sauer et al.
5,897,564	A	*	4/1999	Schulze et al. 606/148
5,908,428	A		6/1999	Scirica et al.
5,908,429	A	*	6/1999	Yoon 606/144
5,919,128	A		7/1999	Fitch
5,961,440	A		10/1999	Schweich, Jr. et al.
5,972,004	A		10/1999	Williamson
5,972,030	A		10/1999	Garrison et al.
5,984,939	A		11/1999	Yoon
5,993,466	A		11/1999	Yoon
5,993,467	A		11/1999	Yoon
6,022,360	A		2/2000	Reimels et al.
6,045,497	A		4/2000	Schweich, Jr. et al.
6,050,936	A		4/2000	Schweich, Jr. et al.
6,053,933	A		4/2000	Balazs
6,059,715	A		5/2000	Schweich, Jr. et al.
6,077,214	A		6/2000	Mortier et al.
6,117,144	A		9/2000	Nobles et al.
6,129,683	A		10/2000	Sutton et al.
6,149,660	A		11/2000	Laufer et al.
6,152,934	A	*	11/2000	Harper et al. 606/139
6,162,168	A		12/2000	Schweich, Jr. et al.
6,162,233	A		12/2000	Williamson
6,165,119	A		12/2000	Schweich, Jr. et al.
6,165,120	A		12/2000	Schweich, Jr. et al.
6,165,183	A		12/2000	Kuehn et al.
6,178,346	B1		1/2001	Amundson et al.
6,183,411	B1		2/2001	Mortier et al.
6,190,357	B1		2/2001	Ferrari et al.
6,234,995	B1		5/2001	Peacock, III
6,245,079	B1		6/2001	Nobles et al.
6,260,552	B1		7/2001	Mortier et al.
6,261,222	B1		7/2001	Schweich, Jr. et al.
6,264,602	B1		7/2001	Mortier et al.
6,269,819	B1		8/2001	Oz et al.
6,270,508	B1		8/2001	Klieman
6,283,993	B1		9/2001	Cosgrove et al.
6,312,447	B1		11/2001	Grimes
6,332,863	B1		12/2001	Schweich, Jr. et al.
6,332,864	B1		12/2001	Schweich, Jr. et al.
6,332,893	B1		12/2001	Mortier et al.
6,355,050	B1		3/2002	Andreas et al.
6,401,720	B1		6/2002	Stevens et al.
6,402,679	B1		6/2002	Mortier et al.
6,402,680	B2		6/2002	Mortier et al.
6,402,781	B1		6/2002	Langberg et al.
6,406,420	B1		6/2002	McCarthy et al.
6,419,626	B1		7/2002	Yoon
6,436,107	B1		8/2002	Wang et al.
6,443,922	B1		9/2002	Roberts et al.
6,451,054	B1		9/2002	Stevens
6,461,366	B1		10/2002	Seguin
6,508,777	B1		1/2003	Macoviak et al.
6,514,194	B2		2/2003	Schweich, Jr. et al.
6,533,796	B1	*	3/2003	Sauer et al. 606/144
6,537,198	B1		3/2003	Vidlund et al.
6,537,314	B2		3/2003	Langberg et al.
6,551,331	B2		4/2003	Nobles et al.
6,558,416	B2		5/2003	Cosgrove et al.
6,562,052	B2		5/2003	Nobles et al.
6,564,805	B2		5/2003	Garrison et al.
6,582,388	B1		6/2003	Coleman et al.
6,585,727	B1		7/2003	Cashman et al.
6,589,160	B2		7/2003	Schweich, Jr. et al.
6,602,288	B1		8/2003	Cosgrove et al.
6,616,684	B1		9/2003	Vidlund
6,619,291	B2		9/2003	Hlavka et al.
6,622,730	B2		9/2003	Ekvall et al.
6,626,917	B1		9/2003	Craig
6,626,930	B1		9/2003	Allen et al.
6,629,534	B1		10/2003	St. Goar et al.
6,629,921	B1		10/2003	Schweich, Jr. et al.
6,629,984	B1		10/2003	Chan
6,645,205	B2		11/2003	Ginn
6,679,268	B2		1/2004	Stevens et al.
6,692,605	B2		2/2004	Kerr et al.
6,695,866	B1		2/2004	Kuehn et al.
6,709,456	B2		3/2004	Langberg et al.
6,718,985	B2		4/2004	Hlavka et al.
6,723,038	B1		4/2004	Schroeder et al.
6,733,509	B2		5/2004	Nobles et al.
6,740,107	B2		5/2004	Loeb et al.
6,746,471	B2		6/2004	Mortier et al.
6,752,813	B2		6/2004	Goldfarb et al.
6,755,777	B2		6/2004	Schweich, Jr. et al.
6,764,510	B2		7/2004	Vidlund et al.
6,770,083	B2		8/2004	Seguin
6,770,084	B1		8/2004	Bain et al.
6,793,618	B2		9/2004	Schweich, Jr. et al.
6,802,860	B2		10/2004	Cosgrove et al.
6,808,488	B2		10/2004	Mortier et al.
6,810,882	B2		11/2004	Langberg et al.
6,840,246	B2		1/2005	Downing
6,858,003	B2		2/2005	Evans
6,875,224	B2		4/2005	Grimes
6,893,448	B2		5/2005	O'Quinn et al.
6,908,424	B2		6/2005	Mortier et al.
6,918,917	B1		7/2005	Nguyen et al.
6,921,407	B2		7/2005	Nguyen et al.
6,929,715	B2		8/2005	Fladda et al.
6,936,054	B2		8/2005	Chu
6,955,175	B2		10/2005	Stevens et al.
6,962,605	B2		11/2005	Cosgrove et al.
6,978,176	B2		12/2005	Lattouf
6,986,775	B2		1/2006	Morales et al.
6,989,028	B2		1/2006	Lashinski et al.
6,991,635	B2		1/2006	Takamoto
6,997,950	B2		2/2006	Chawla
7,004,176	B2		2/2006	Lau
7,004,952	B2		2/2006	Nobles et al.
7,011,669	B2		3/2006	Kimblad
7,044,905	B2		5/2006	Vidlund et al.
7,048,754	B2		5/2006	Martin et al.
7,077,862	B2		7/2006	Vidlund et al.
7,083,628	B2		8/2006	Bachman
7,083,638	B2		8/2006	Foerster
7,090,686	B2		8/2006	Nobles et al.
7,094,244	B2		8/2006	Schreck
7,100,614	B2		9/2006	Stevens et al.
7,112,207	B2		9/2006	Allen et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,112,219	B2	9/2006	Vidlund et al.	
7,118,583	B2	10/2006	O'Quinn et al.	
7,122,040	B2	10/2006	Hill et al.	
7,179,291	B2	2/2007	Rourke et al.	
7,186,264	B2	3/2007	Liddicoat et al.	
7,189,199	B2	3/2007	McCarthy et al.	
7,217,240	B2	5/2007	Snow	
7,226,467	B2	6/2007	Lucatero et al.	
7,247,134	B2	7/2007	Vidlund et al.	
7,250,028	B2	7/2007	Julian et al.	
7,288,097	B2	10/2007	Sé quin	
7,294,148	B2	11/2007	McCarthy	
7,381,210	B2	6/2008	Zarbatany et al.	
7,464,712	B2	12/2008	Oz et al.	
7,563,267	B2	7/2009	Goldfarb et al.	
7,563,273	B2	7/2009	Goldfarb et al.	
7,604,646	B2	10/2009	Goldfarb et al.	
7,608,091	B2	10/2009	Goldfarb et al.	
7,635,386	B1	12/2009	Gammie	
7,666,204	B2	2/2010	Thornton	
7,815,654	B2	10/2010	Chu	
7,879,048	B2	2/2011	Bain et al.	
7,887,552	B2	2/2011	Bachman	
8,465,500	B2	6/2013	Speziali	
2001/0005787	A1	6/2001	Oz	
2001/0016675	A1	8/2001	Mortier et al.	
2001/0021872	A1	9/2001	Bailey et al.	
2002/0013571	A1	1/2002	Goldfarb et al.	
2002/0029080	A1	3/2002	Mortier et al.	
2002/0049402	A1	4/2002	Peacock, III et al.	
2002/0077524	A1	6/2002	Schweich, Jr. et al.	
2002/0169359	A1	11/2002	McCarthy et al.	
2002/0173694	A1	11/2002	Mortier et al.	
2002/0183766	A1	12/2002	Sequin	
2003/0004562	A1	1/2003	DiCarlo	
2003/0032979	A1	2/2003	Mortier et al.	
2003/0050529	A1	3/2003	Vidlund et al.	
2003/0050693	A1	3/2003	Quijano et al.	
2003/0078600	A1	4/2003	O'Quinn et al.	
2003/0105519	A1	6/2003	Fasol	
2003/0130731	A1	7/2003	Vidlund et al.	
2003/0166992	A1	9/2003	Schweich, Jr. et al.	
2003/0167071	A1	9/2003	Martin et al.	
2003/0171641	A1	9/2003	Schweich, Jr. et al.	
2003/0181928	A1	9/2003	Vidlund et al.	
2003/0187457	A1	10/2003	Weber	
2003/0195529	A1	10/2003	Takamoto et al.	
2003/0199975	A1	10/2003	Gabbay	
2004/0003819	A1	1/2004	St. Goar et al.	
2004/0030382	A1	2/2004	St. Goar et al.	
2004/0039442	A1	2/2004	St. Goar et al.	
2004/0044350	A1	3/2004	Martin et al.	
2004/0044365	A1	3/2004	Bachman	
2004/0049207	A1	3/2004	Goldfarb et al.	
2004/0049552	A1	3/2004	Motoyama et al.	
2004/0087975	A1	5/2004	Lucatero et al.	
2004/0087978	A1	5/2004	Velez et al.	
2004/0092962	A1	5/2004	Thornton et al.	
2004/0122448	A1	6/2004	Levine	
2004/0127983	A1	7/2004	Mortier et al.	
2004/0133063	A1	7/2004	McCarthy et al.	
2004/0167374	A1	8/2004	Schweich et al.	
2004/0167539	A1	8/2004	Kuehn et al.	
2004/0225300	A1	11/2004	Goldfarb et al.	
2004/0225304	A1	11/2004	Vidlund et al.	
2004/0236353	A1	11/2004	Bain	
2004/0236354	A1	11/2004	Seguin	
2004/0243229	A1	12/2004	Vidlund et al.	
2004/0267083	A1	12/2004	McCarthy et al.	
2005/0004668	A1	1/2005	Aklog et al.	
2005/0021055	A1	1/2005	Toubia	
2005/0021056	A1	1/2005	St. Goar et al.	
2005/0021057	A1	1/2005	St. Goar et al.	
2005/0033446	A1	2/2005	Deem et al.	
2005/0044365	A1	2/2005	Bachman	
2005/0065396	A1	3/2005	Mortier et al.	
2005/0075723	A1	4/2005	Schroeder et al.	
2005/0075727	A1	4/2005	Wheatley	
2005/0101975	A1	5/2005	Nguyen et al.	
2005/0125011	A1	6/2005	Spence et al.	
2005/0131277	A1	6/2005	Schweich, Jr. et al.	
2005/0131533	A1	6/2005	Alfieri et al.	
2005/0143620	A1	6/2005	Mortier et al.	
2005/0148815	A1	7/2005	Mortier et al.	
2005/0149014	A1	7/2005	Hauck et al.	
2005/0154402	A1	7/2005	Sauer et al.	
2005/0165419	A1*	7/2005	Sauer et al.	606/148
2005/0171601	A1	8/2005	Cosgrove et al.	
2005/0216039	A1	9/2005	Lederman	
2005/0240202	A1	10/2005	Shennib et al.	
2005/0251187	A1	11/2005	Beane et al.	
2006/0020275	A1	1/2006	Goldfarb et al.	
2006/0036317	A1	2/2006	Vidlund et al.	
2006/0041306	A1	2/2006	Vidlund et al.	
2006/0052868	A1	3/2006	Mortier et al.	
2006/0058871	A1	3/2006	Zakay et al.	
2006/0069304	A1*	3/2006	Takemoto et al.	600/104
2006/0074485	A1	4/2006	Realyvasquez	
2006/0089671	A1	4/2006	Goldfarb et al.	
2006/0100699	A1	5/2006	Vidlund et al.	
2006/0127509	A1	6/2006	Eckman et al.	
2006/0135993	A1	6/2006	Seguin	
2006/0149123	A1	7/2006	Vidlund et al.	
2006/0161040	A1	7/2006	McCarthy et al.	
2006/0161193	A1	7/2006	Beane et al.	
2006/0184203	A1	8/2006	Martin et al.	
2006/0195012	A1	8/2006	Mortier et al.	
2006/0195134	A1	8/2006	Crittenden	
2006/0195183	A1	8/2006	Navia et al.	
2006/0241340	A1	10/2006	Vidlund et al.	
2006/0287657	A1	12/2006	Bachman	
2007/0002627	A1	1/2007	Youn	
2007/0027451	A1	2/2007	Desinger et al.	
2007/0049952	A1	3/2007	Weiss	
2007/0050022	A1	3/2007	Vidlund et al.	
2007/0055303	A1	3/2007	Vidlund et al.	
2007/0088375	A1	4/2007	Beane et al.	
2007/0100356	A1	5/2007	Lucatero et al.	
2007/0112244	A1	5/2007	McCarthy et al.	
2007/0118154	A1	5/2007	Crabtree	
2007/0118155	A1	5/2007	Goldfarb et al.	
2007/0129737	A1	6/2007	Goldfarb et al.	
2007/0179511	A1	8/2007	Paolitto	
2007/0197858	A1	8/2007	Goldfarb et al.	
2007/0203391	A1	8/2007	Bloom et al.	
2007/0232941	A1	10/2007	Rabinovich	
2007/0239272	A1	10/2007	Navia et al.	
2007/0265643	A1	11/2007	Beane et al.	
2007/0299468	A1	12/2007	Viola	
2008/0027468	A1	1/2008	Fenton	
2008/0051703	A1	2/2008	Thornton et al.	
2008/0065011	A1	3/2008	Marchand et al.	
2008/0065156	A1	3/2008	Hauser et al.	
2008/0065205	A1	3/2008	Nguyen et al.	
2008/0091059	A1	4/2008	Machold et al.	
2008/0091264	A1	4/2008	Machold et al.	
2008/0097482	A1	4/2008	Bain et al.	
2008/0097489	A1	4/2008	Goldfarb et al.	
2008/0167714	A1	7/2008	St. Goar et al.	
2008/0183194	A1	7/2008	Goldfarb et al.	
2008/0188873	A1	8/2008	Speziali	
2008/0195200	A1	8/2008	Vidlund et al.	
2008/0208006	A1	8/2008	Farr	
2008/0228223	A1	9/2008	Alkhatib	
2009/0105729	A1	4/2009	Zentgraf	
2009/0105751	A1	4/2009	Zentgraf	
2009/0131880	A1	5/2009	Speziali et al.	
2009/0156995	A1	6/2009	Martin et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2009/0163934	A1	6/2009	Raschdorf, Jr. et al.
2009/0259304	A1	10/2009	O'Beirne et al.
2010/0042147	A1	2/2010	Janovsky et al.

FOREIGN PATENT DOCUMENTS

EP	1 845 861	A4	10/2007
EP	1845861	A2	10/2007
EP	1 408 850	B1	9/2009
JP	06-142114		5/1994
WO	WO 99/00059		1/1999
WO	WO 99/30647		6/1999
WO	WO 00/06026	A2	2/2000
WO	WO 00/06026	A3	2/2000
WO	WO 00/06027	A2	2/2000
WO	WO 00/06028	A1	2/2000
WO	WO 00/16700		3/2000
WO	WO 01/66018	A1	9/2001
WO	WO 01/95809	A1	12/2001
WO	WO 03/001893	A2	1/2003
WO	WO 03/059209	A2	7/2003
WO	WO 03/082157	A2	10/2003
WO	WO 2004/021893		3/2004
WO	WO 2004/021893	A1	3/2004
WO	WO 2004/043265	A2	5/2004
WO	WO 2005/039428	A2	5/2005
WO	WO 2005/094525	A2	10/2005
WO	WO 2006/032051	A2	3/2006
WO	WO 2006/065966	A2	6/2006
WO	WO 2006/078694	A2	7/2006
WO	WO 2006/116310	A2	11/2006
WO	WO 2006/127509	A2	11/2006
WO	WO 2007/002627	A1	1/2007
WO	WO 2007/027451	A2	3/2007
WO	WO 2007/062128	A2	5/2007
WO	WO 2007/081418	A1	7/2007
WO	WO 2007/117612	A1	10/2007
WO	WO 2008/010738	A2	1/2008
WO	WO 2009/052528	A2	4/2009

OTHER PUBLICATIONS

Port Access System for Mitral Valve Repair Proves Its Value in Study; MedGadget Jul. 9, 2009; available at: http://www.medgadget.com/archives/2009/07 port access system for mitral valve repair proves its value in study.html (5 pages).

File History for U.S. Appl. No. 12/254,808; Published Apr. 23, 2009; John Zentgraf.

International Search Report for International Application No. PCT/US2008/080560 (Aug. 25, 2009) 3 pages.

International Search Report for International Application No. PCT/US2008/080560 (Aug. 28, 2009) 2 pages.

Written Opinion of the International Search Authority, International Application No. PCT /US/2008/080560, Filed Oct. 20, 2008, Date of Completion: Aug. 24, 2009.

European Search Report, European Application No. 08839048.9, dated Sep. 16, 2010, 7 pages.

Extended European Search Report, EP 06718728.6, Nov. 11, 2009, 7 pages.

Machine translation of JP 06142114, 9 pages.

PCT International Preliminary Report on Patentability/Written Opinion for PCT/US2008/080560, dated Apr. 20, 2010, 6 pages.

PCT International Search Report and Written Opinion, PCT/US06/01699, May 6, 2008.

PCT International Search Report, PCT/US2008/080560, dated Aug. 25, 2009, 3 pages.

PCT International Search Report, PCT/US2008/080560, dated Aug. 28, 2009, 2 pages.

US 6,197,052, 03/2001, Cosgrove et al. (withdrawn)

* cited by examiner

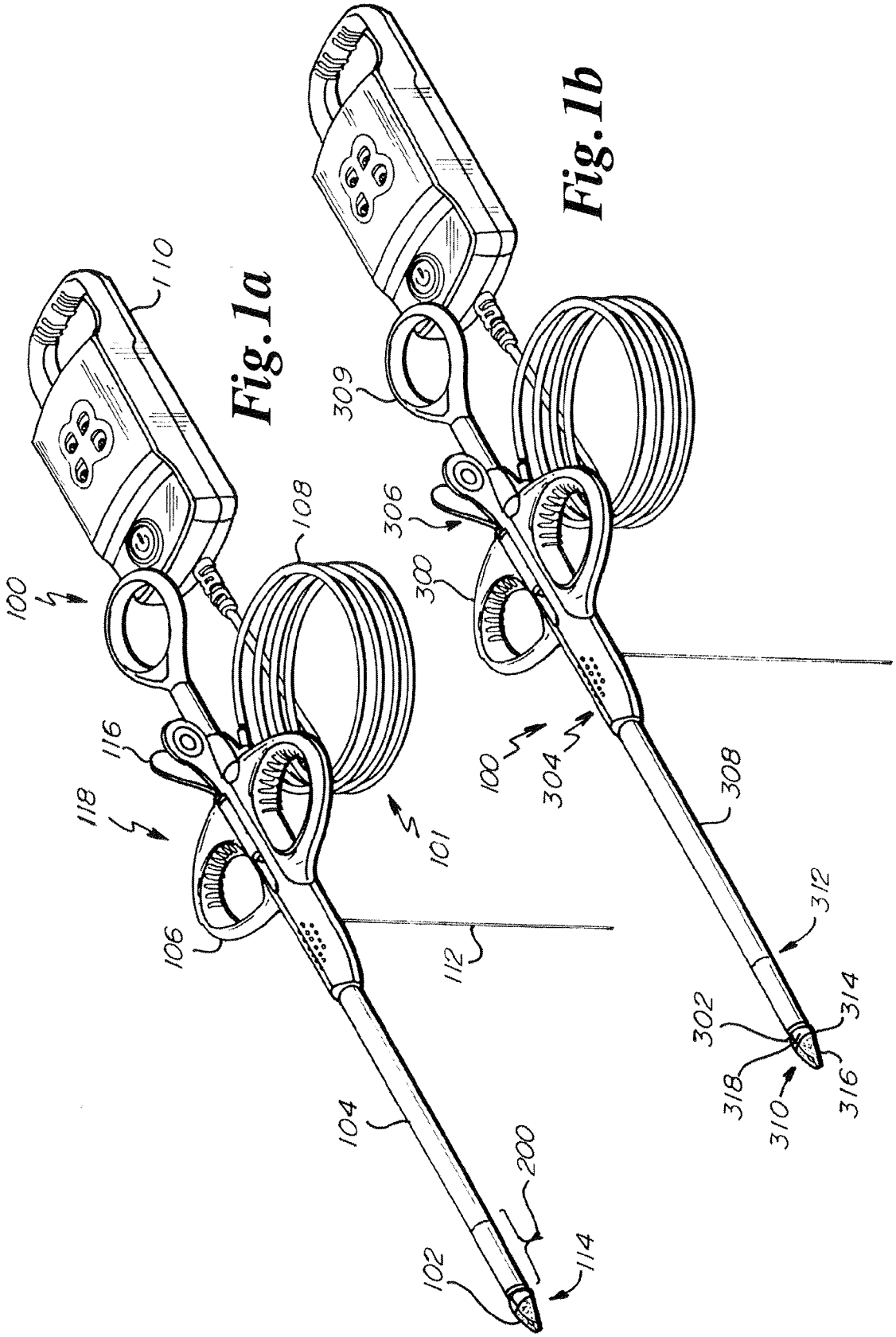


Fig. 1a
Fig. 1b
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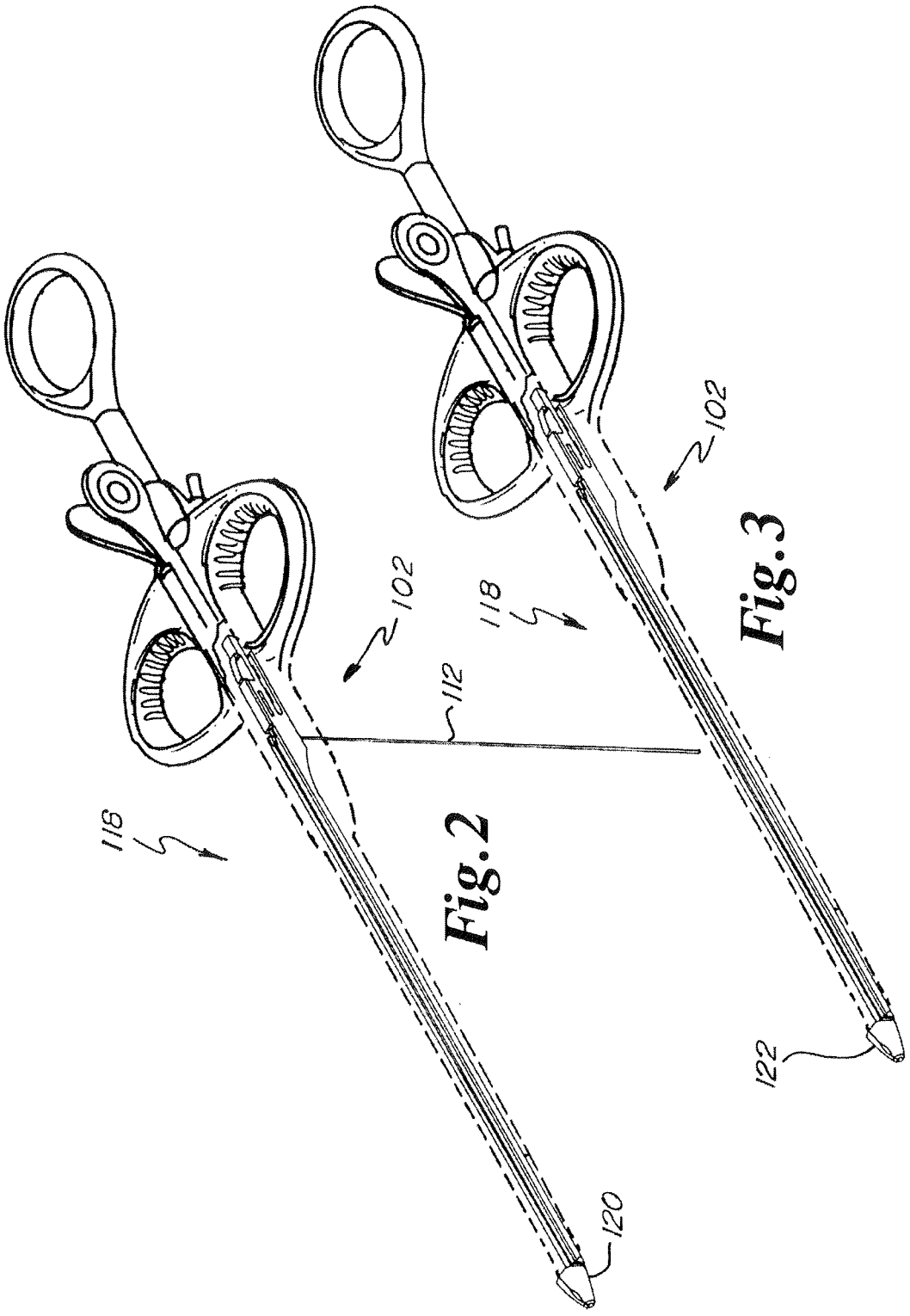
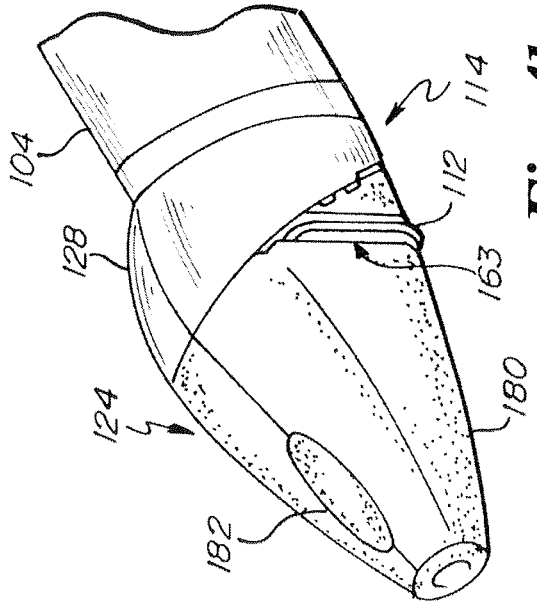


Fig. 2

Fig. 3



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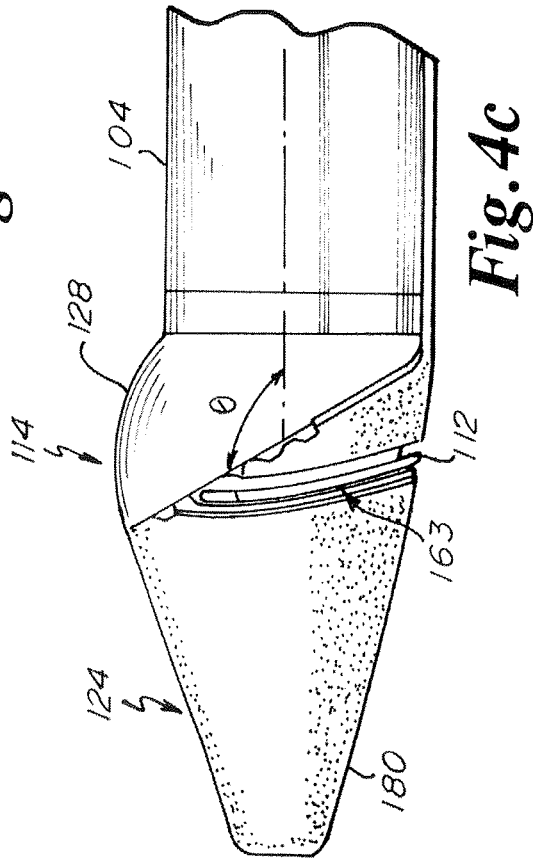

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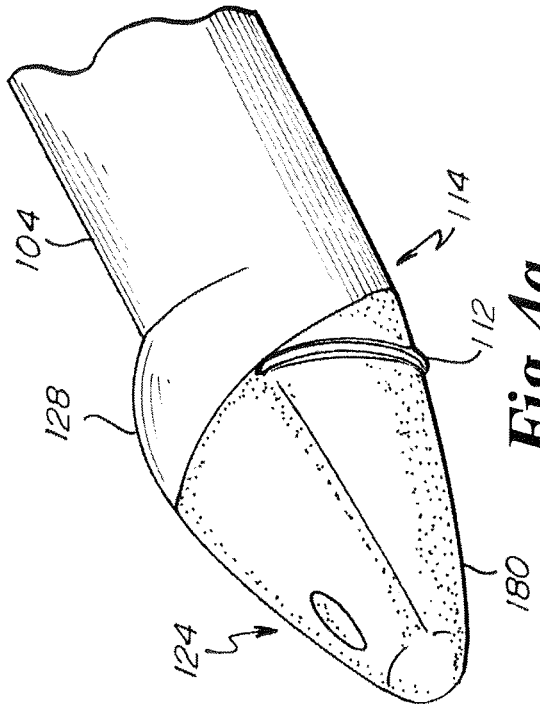

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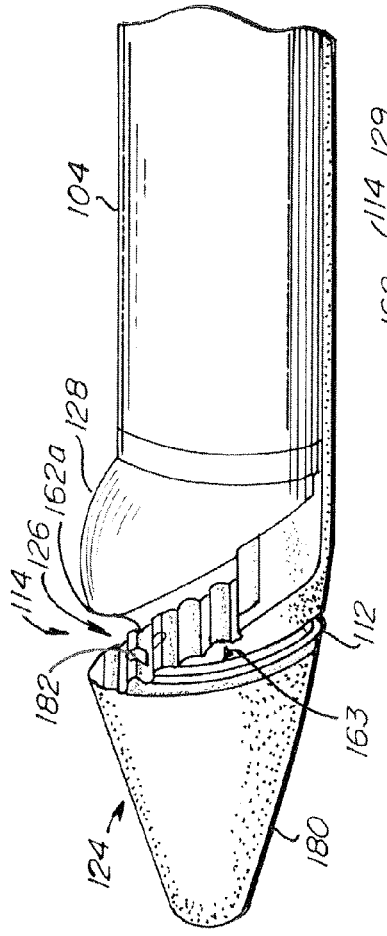

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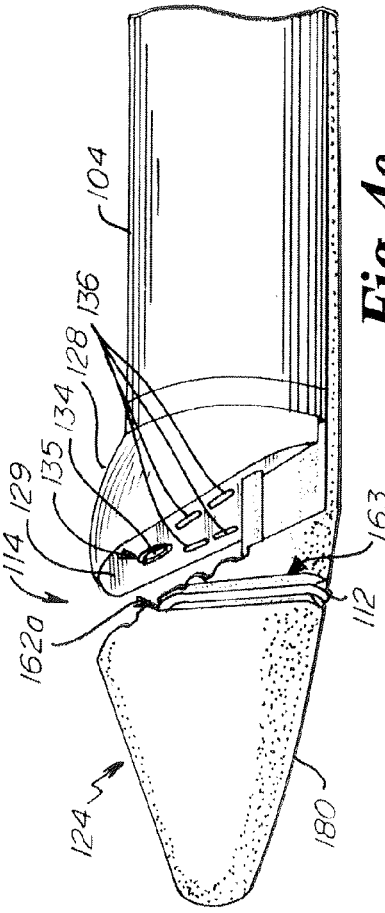

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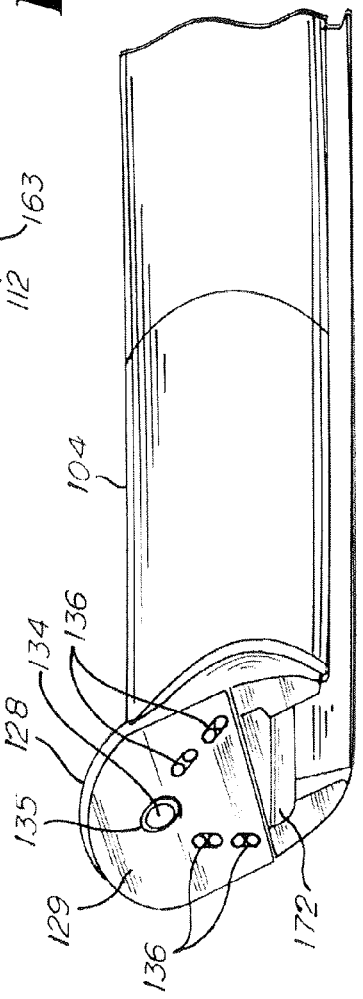

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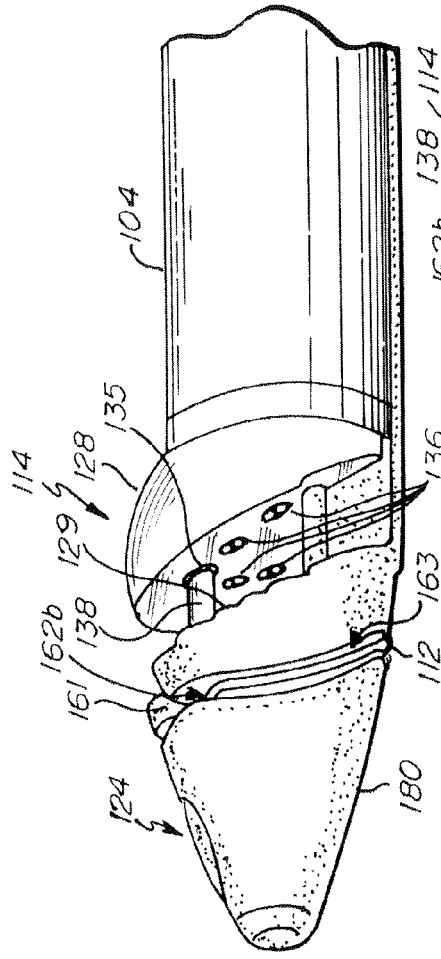

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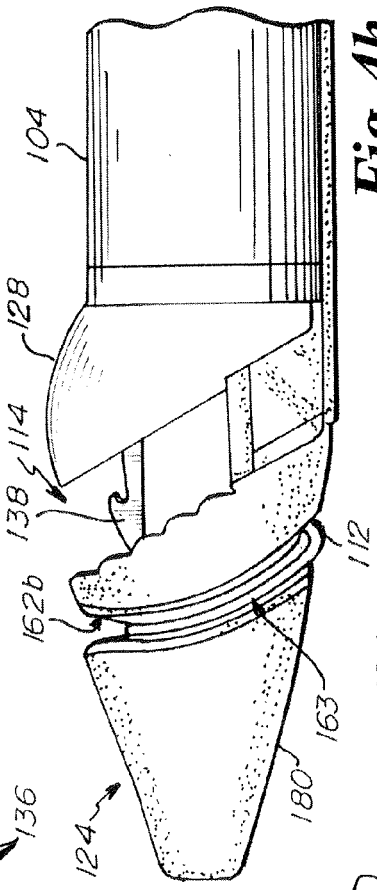

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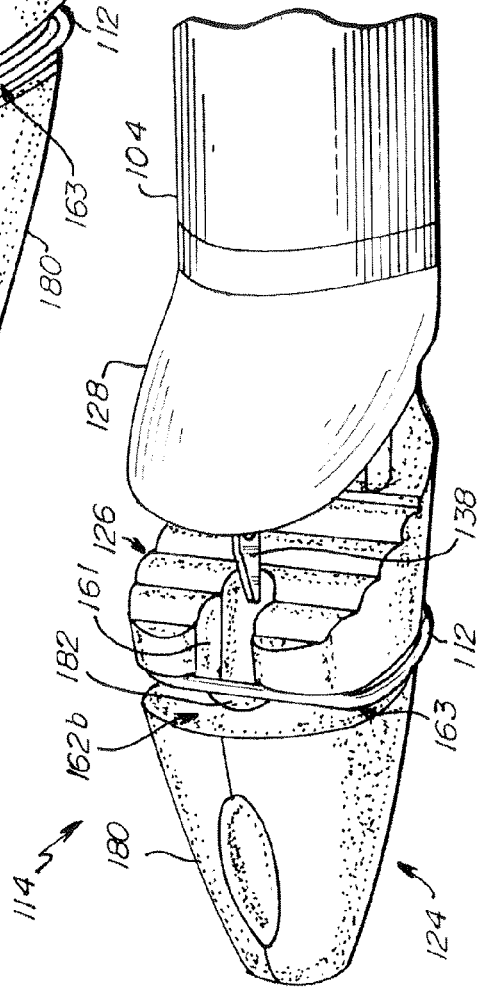

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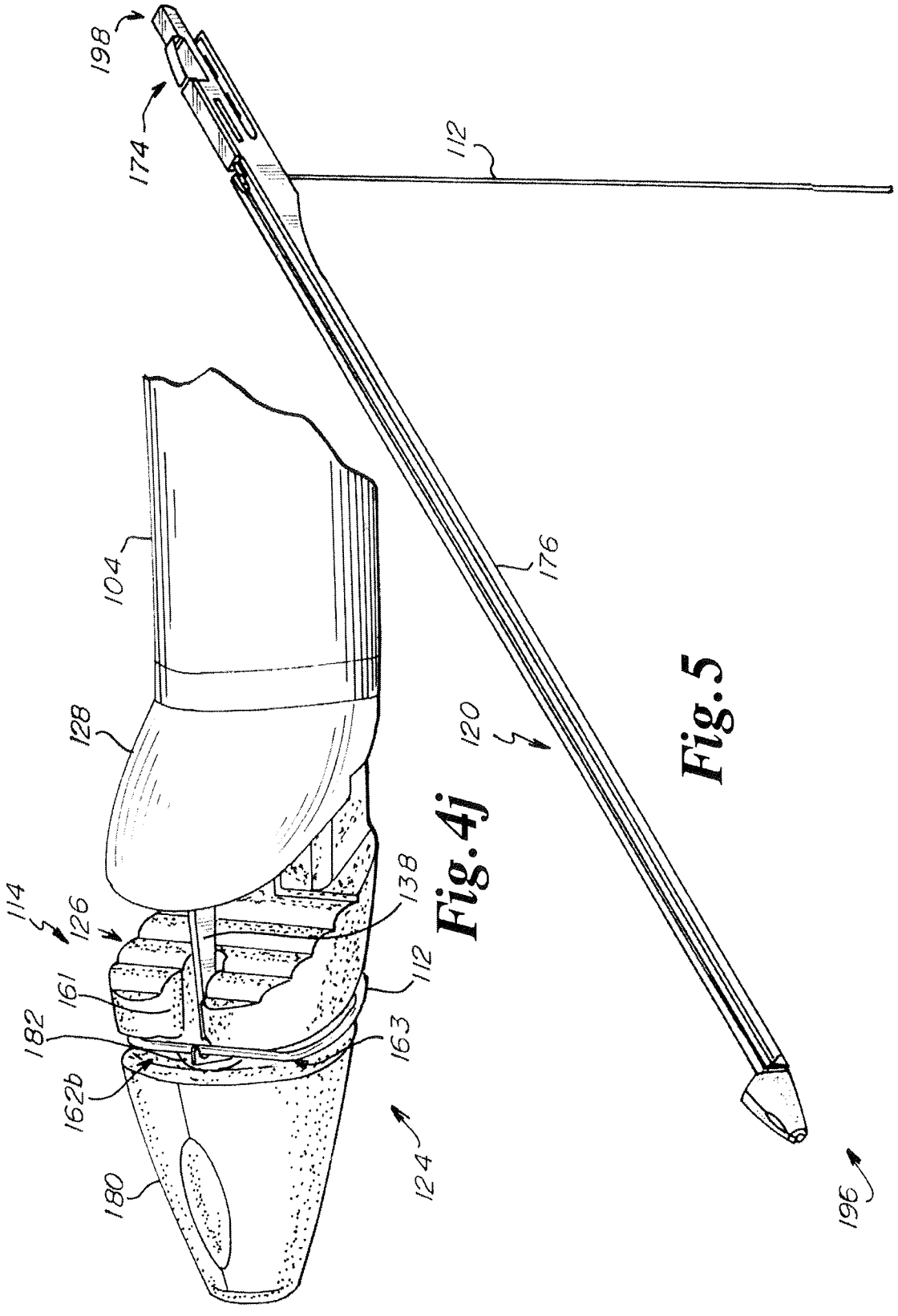
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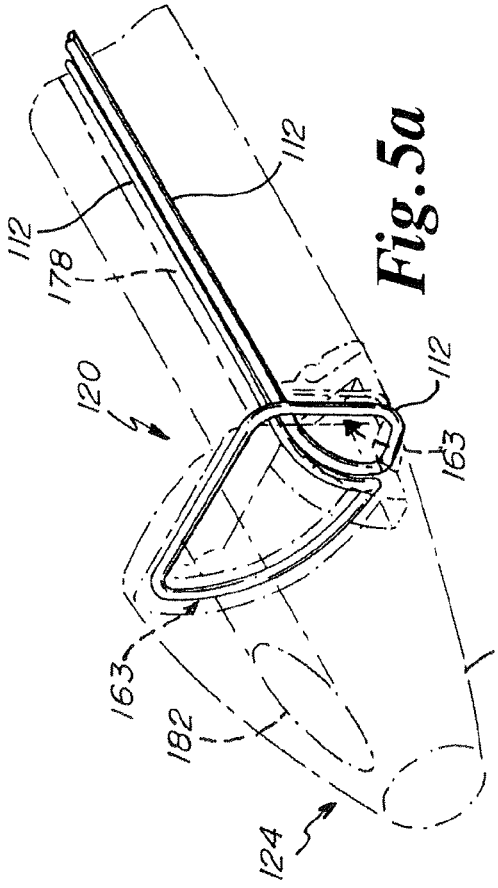
Fig.4j

Fig.5



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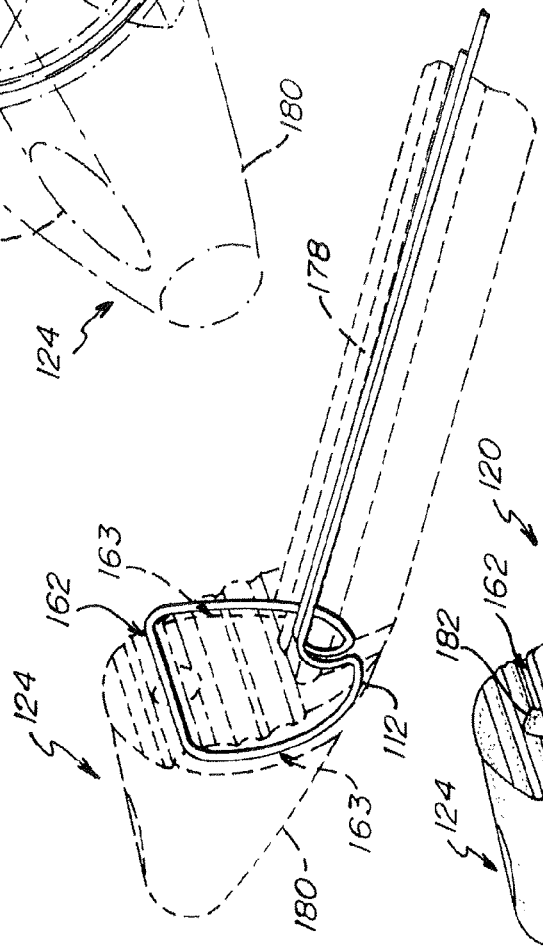


Fig. 5c

Fig. 5d

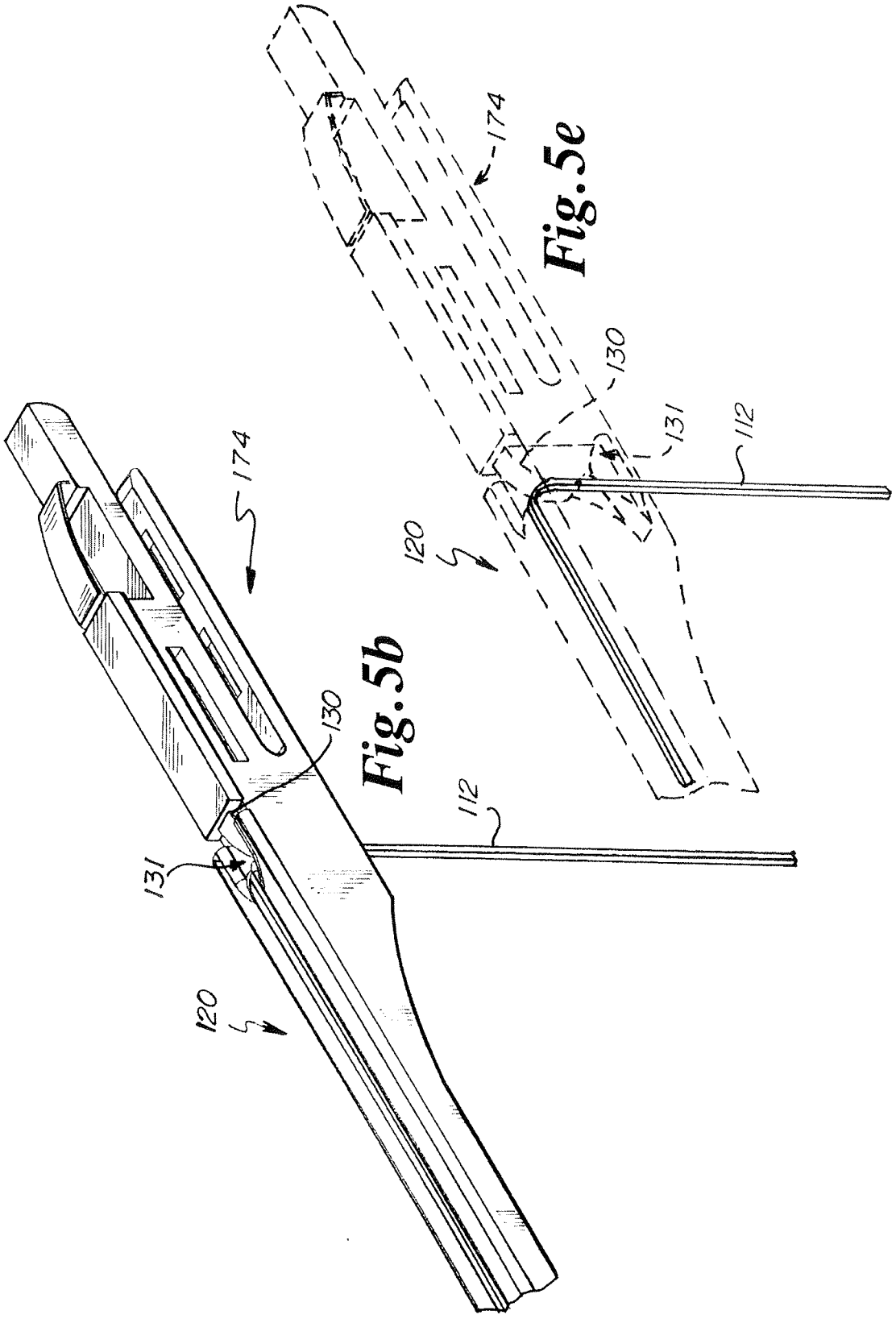


Fig. 5e

Fig. 5b

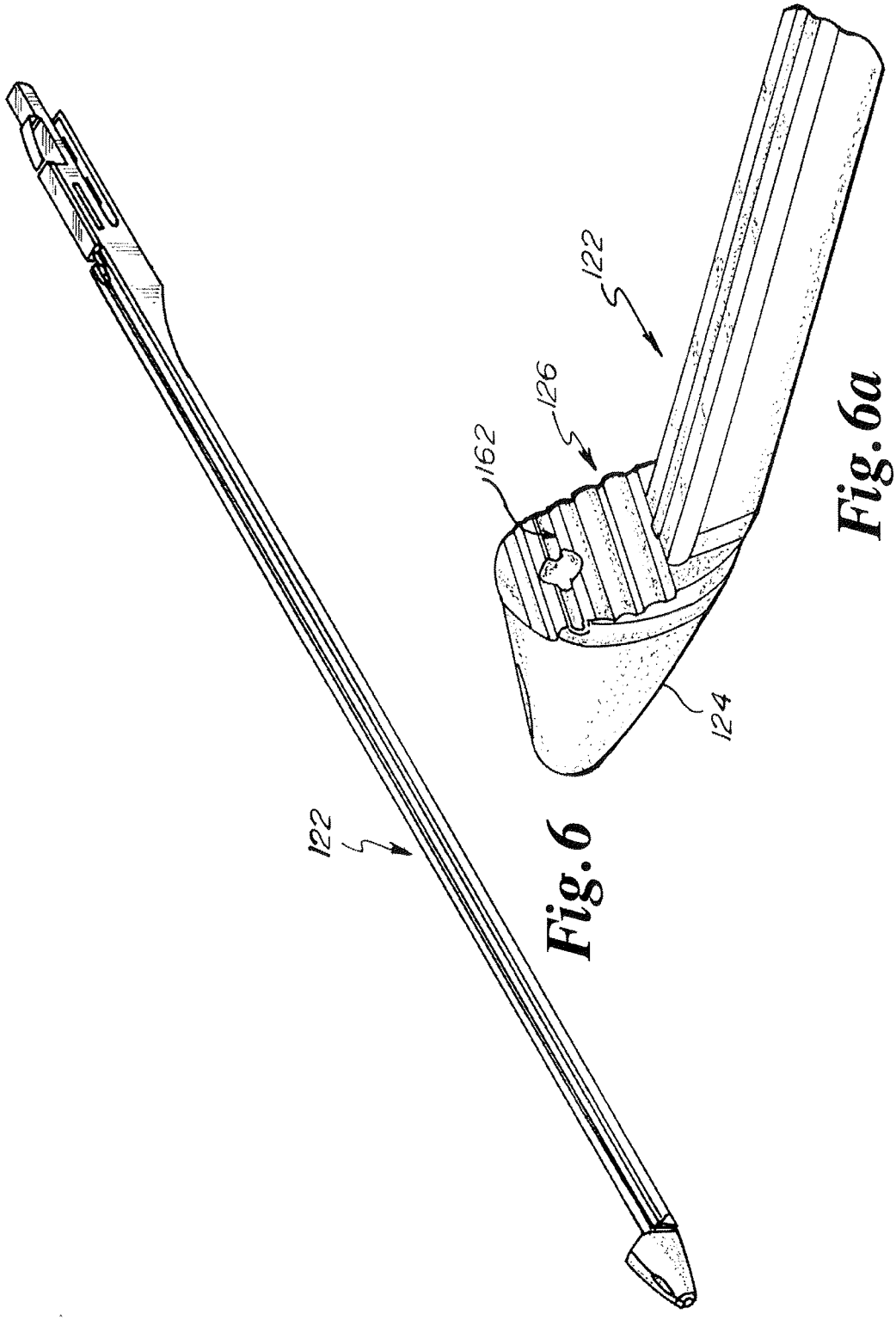


Fig. 6a

Fig. 6

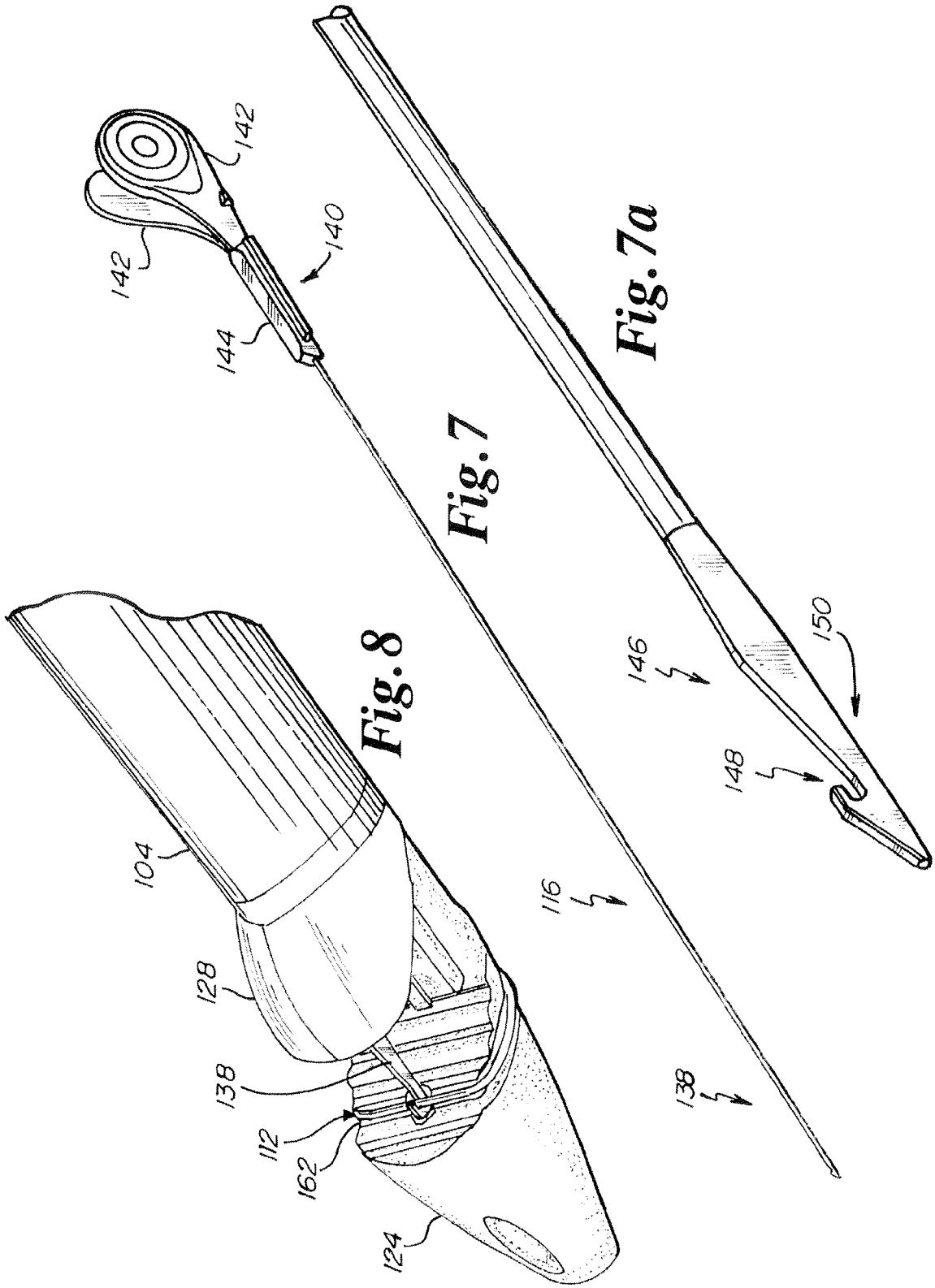


Fig. 8

Fig. 7

Fig. 7a

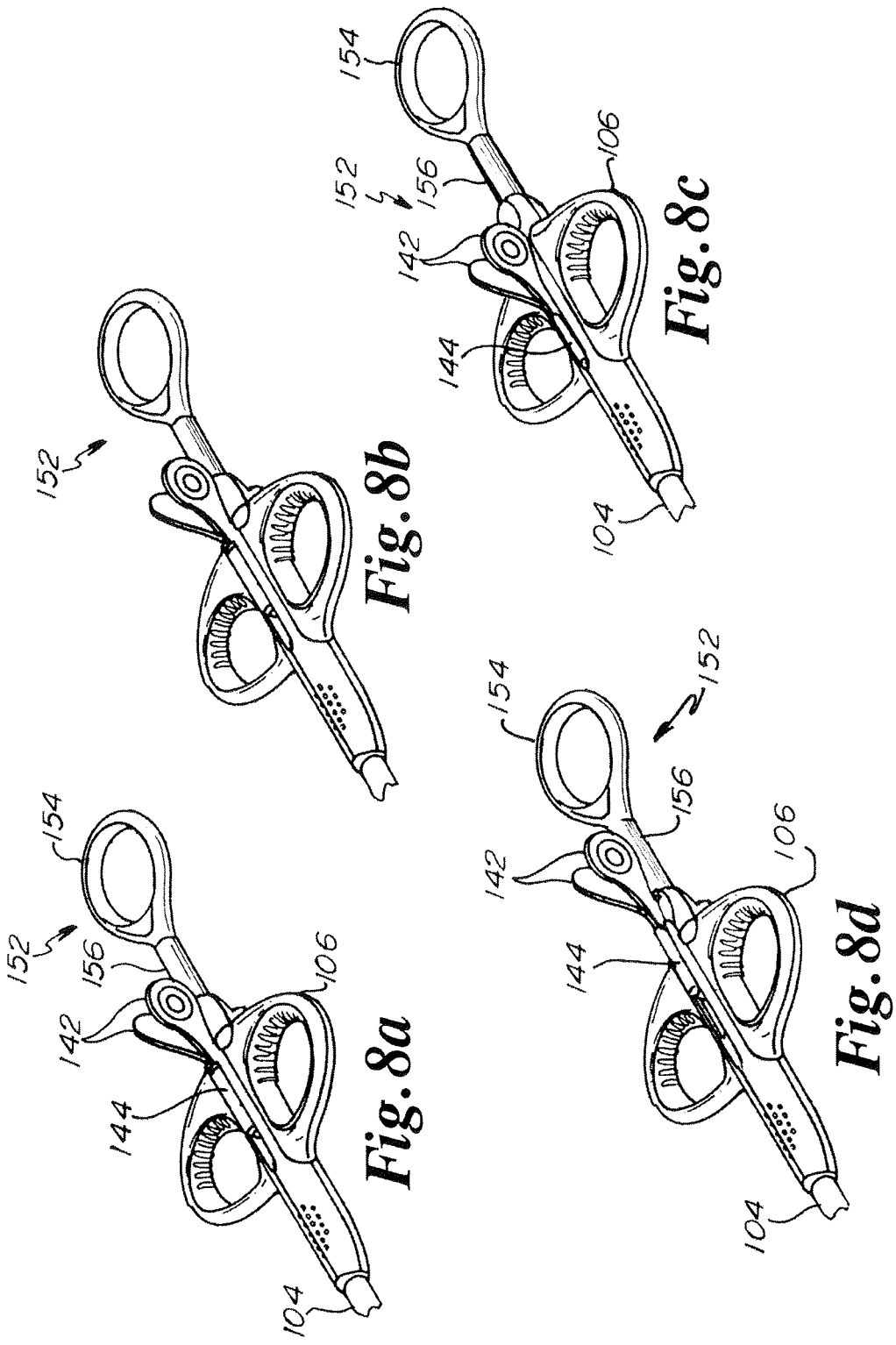


Fig. 8a

Fig. 8b

Fig. 8c

Fig. 8d

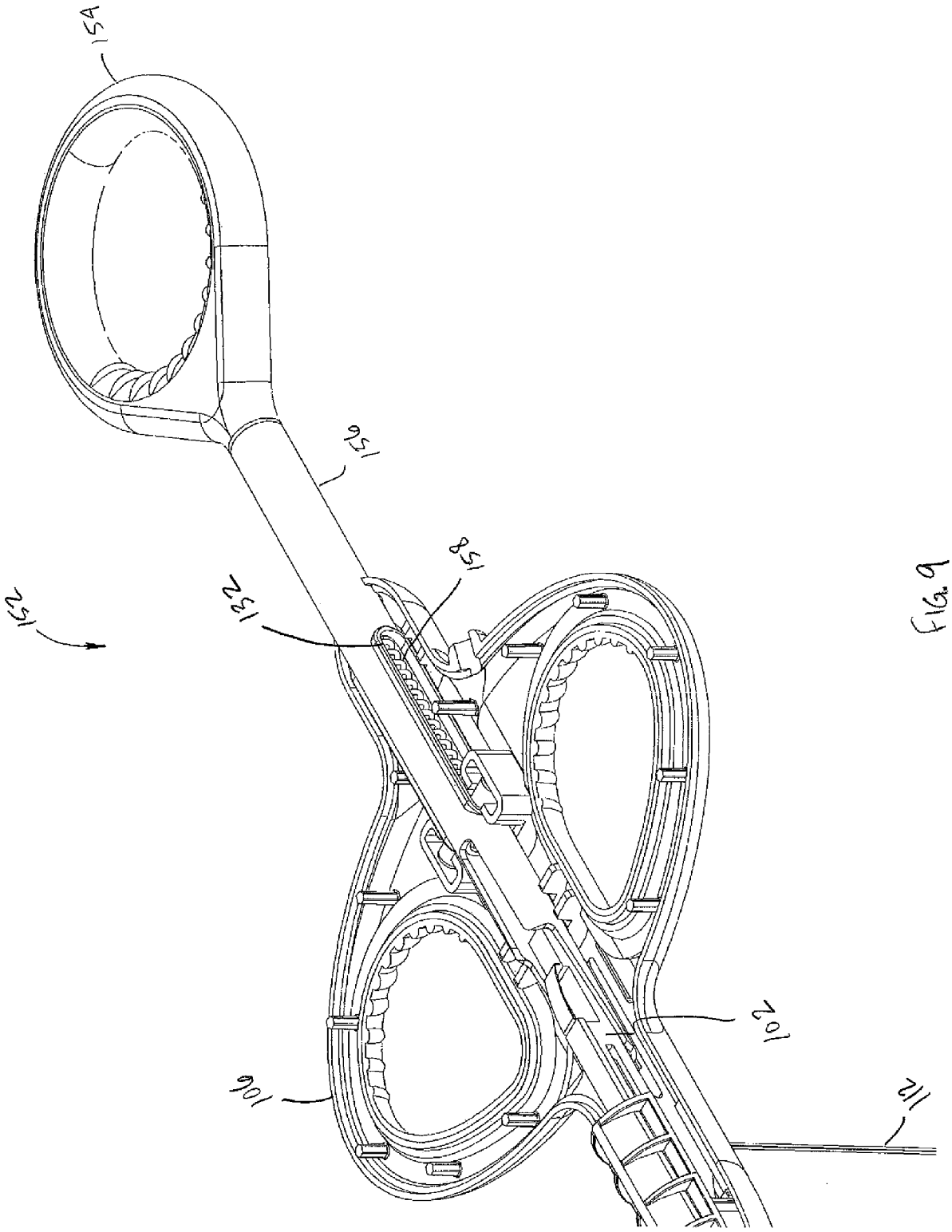


FIG. 9

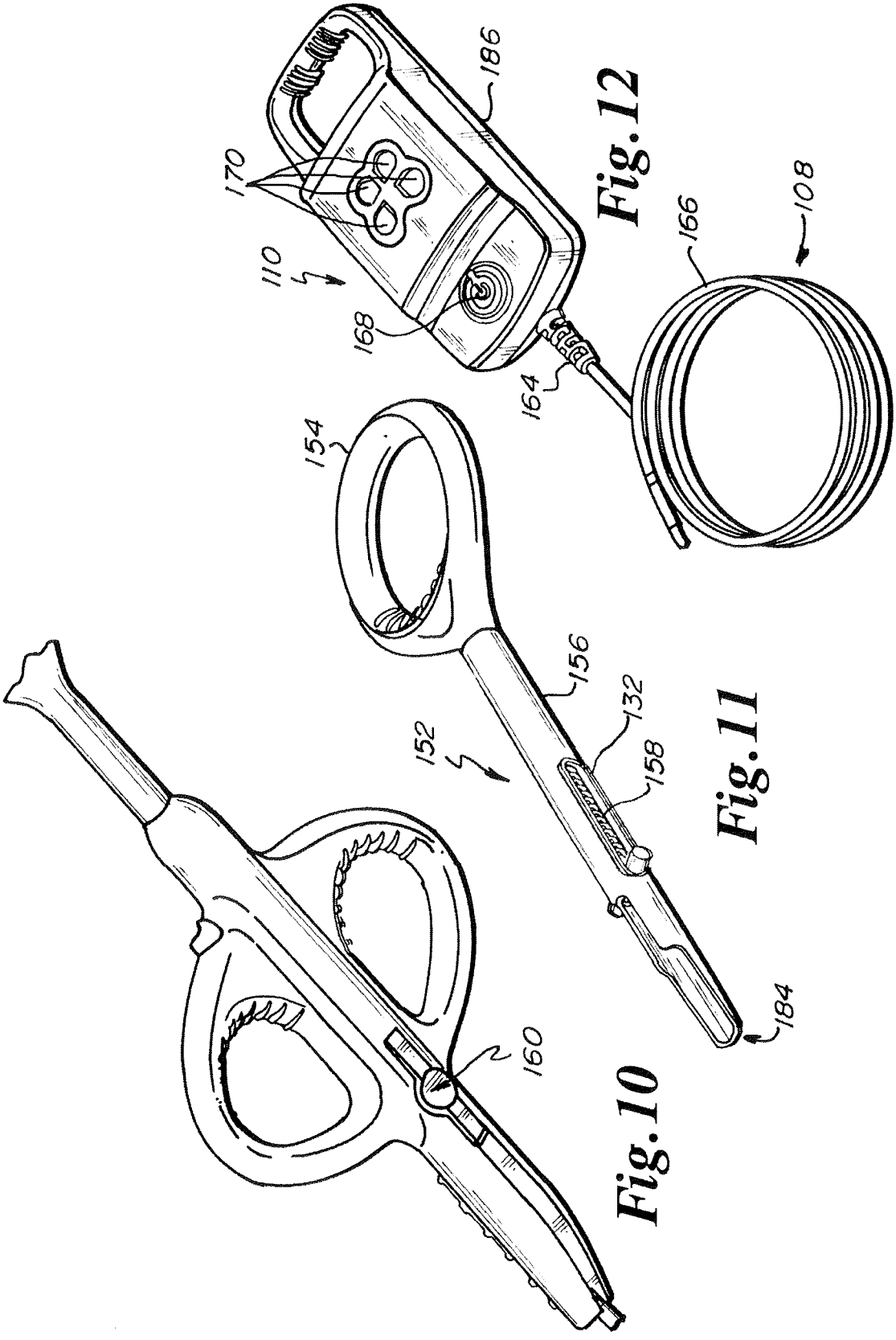
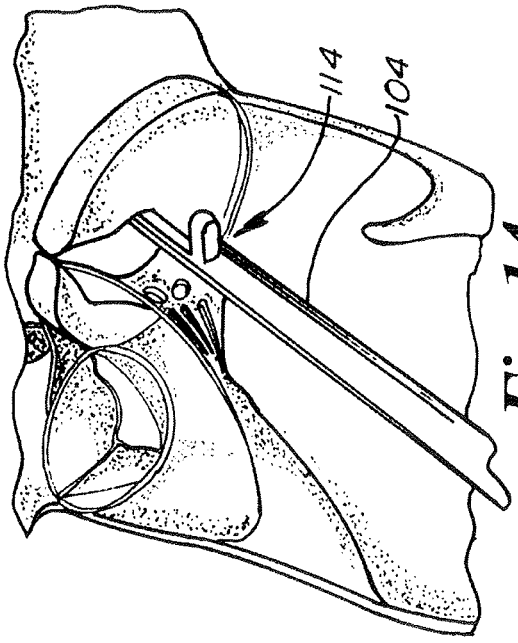


Fig. 12

Fig. 11

Fig. 10



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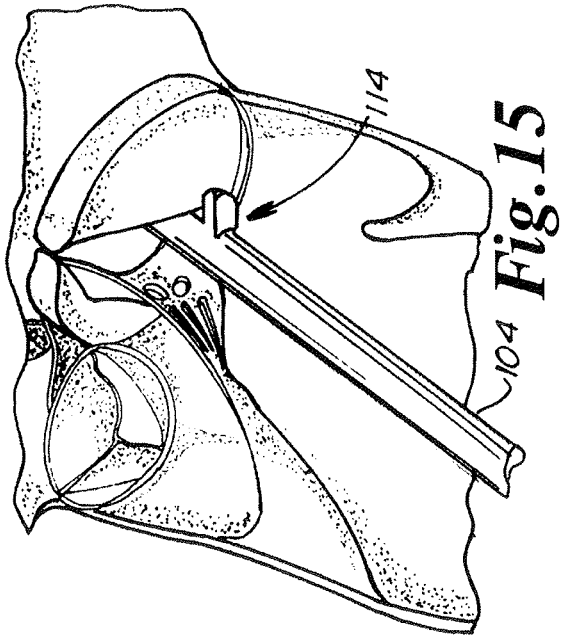

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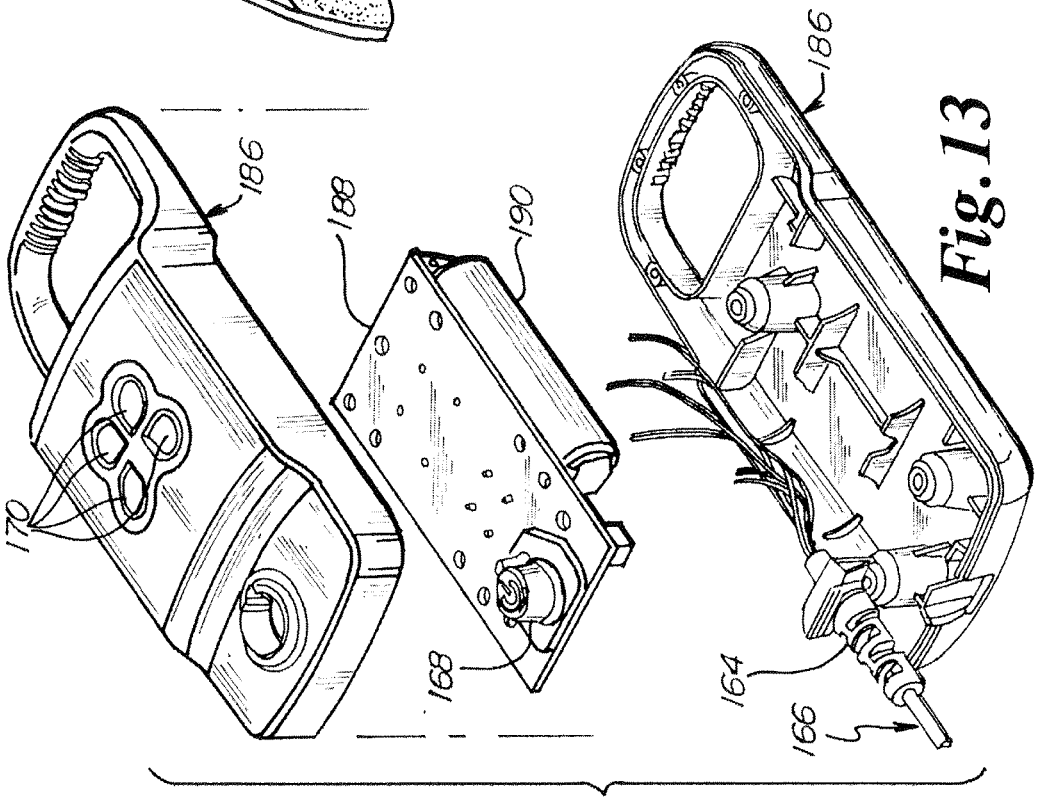

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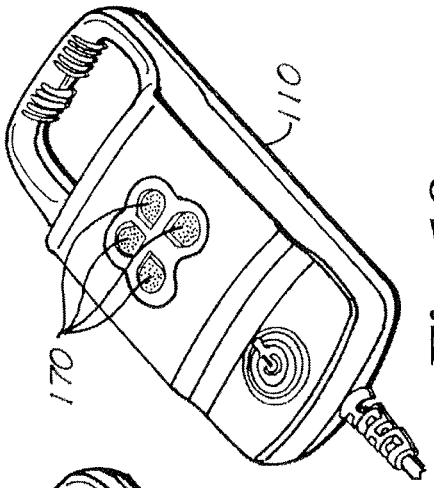

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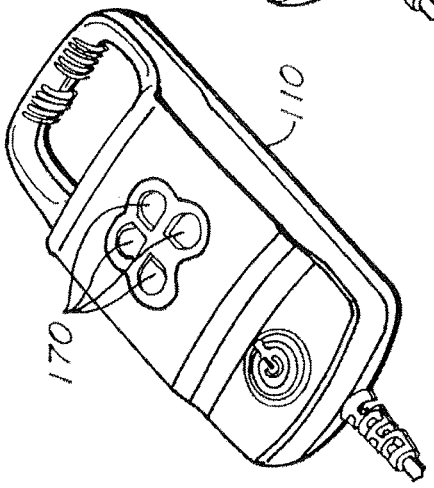

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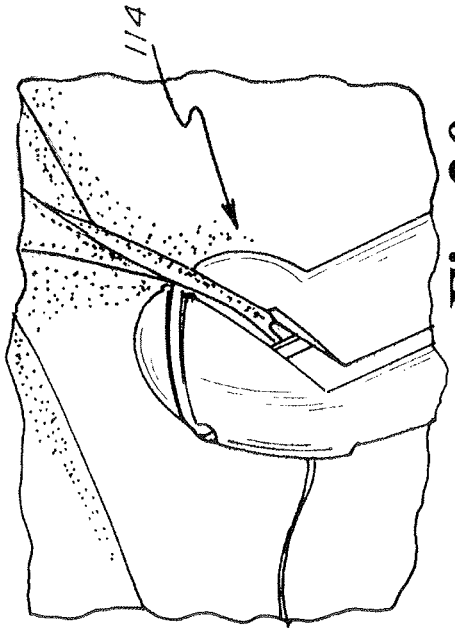

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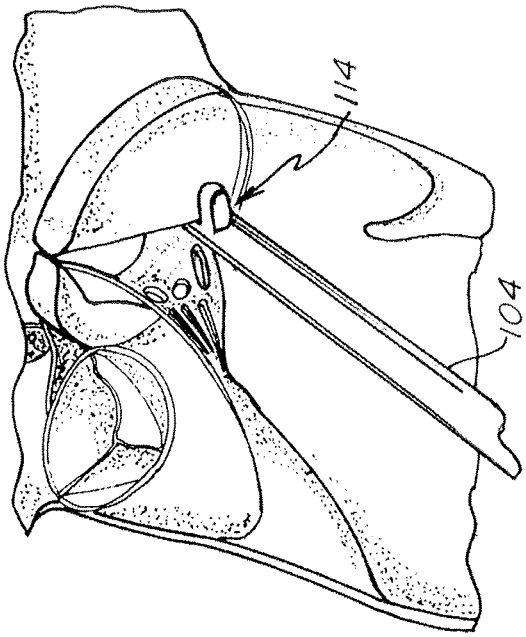

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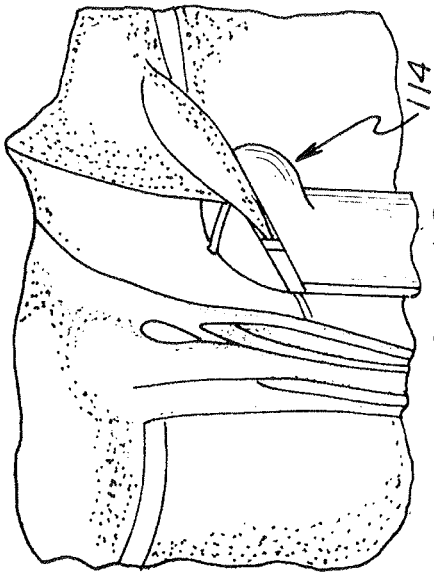

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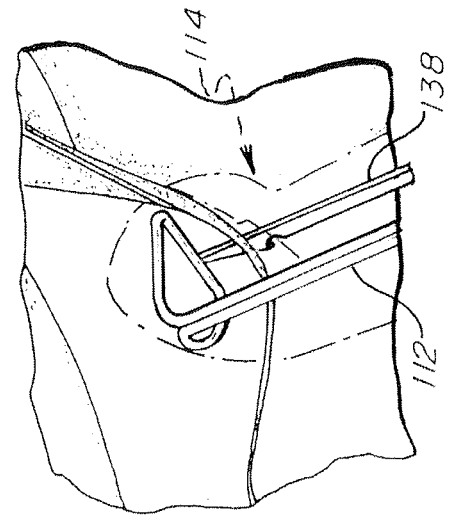

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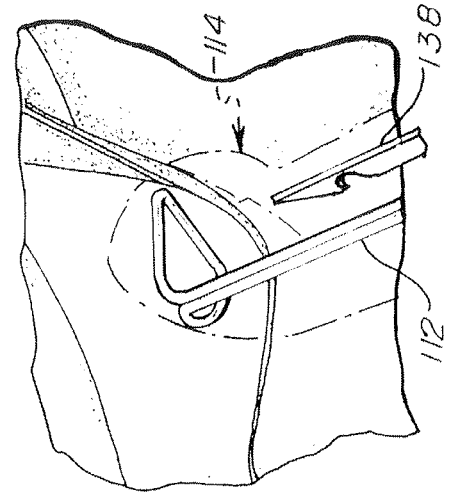

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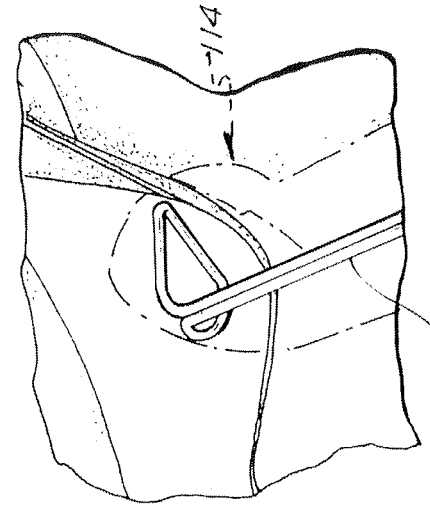

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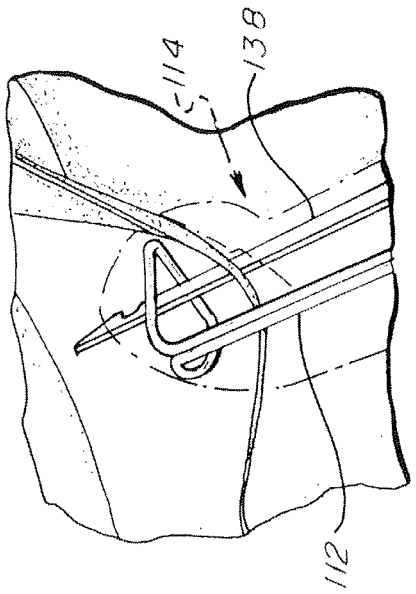

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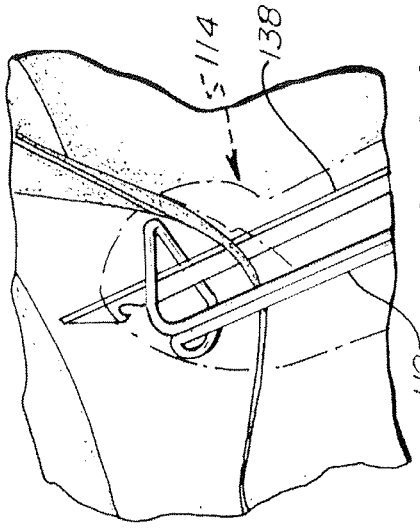

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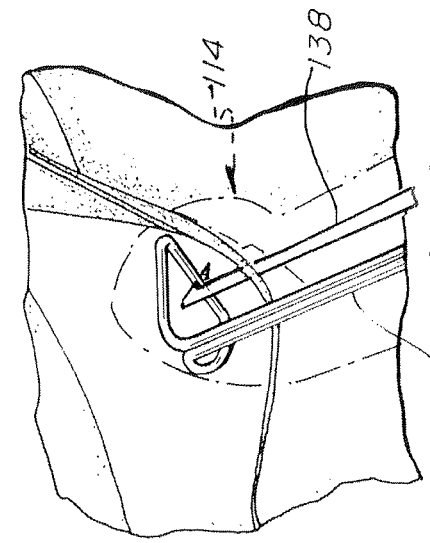

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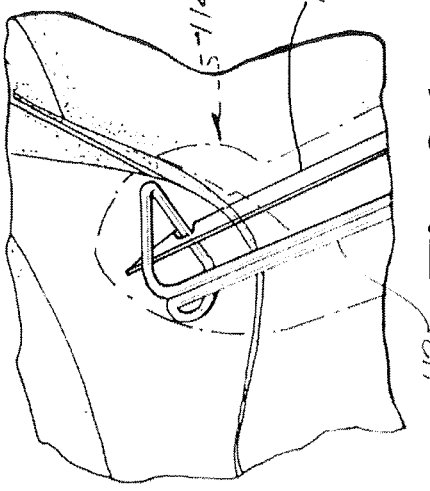

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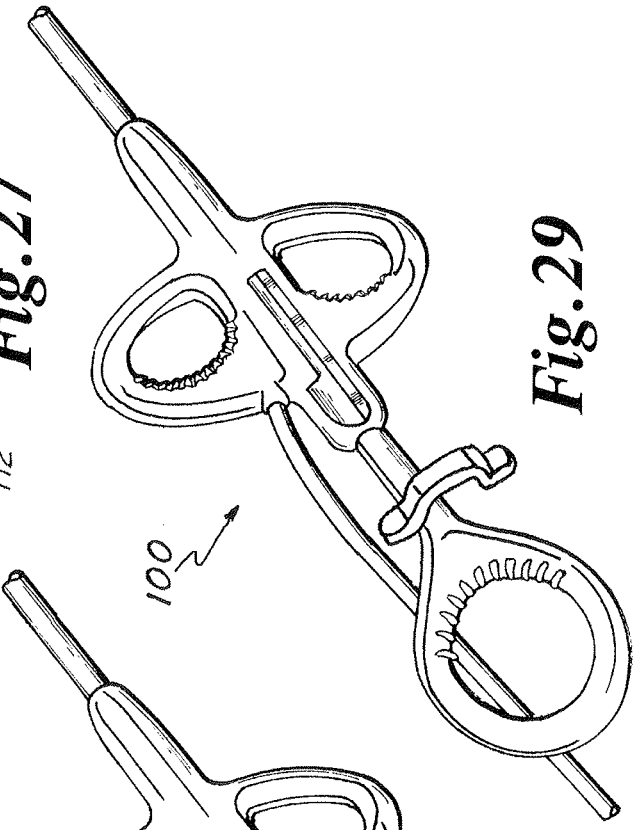

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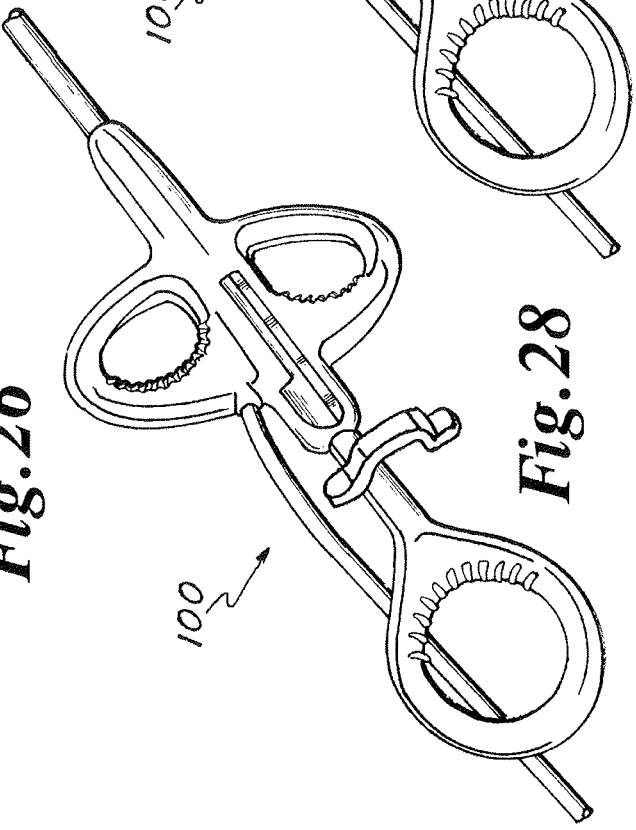

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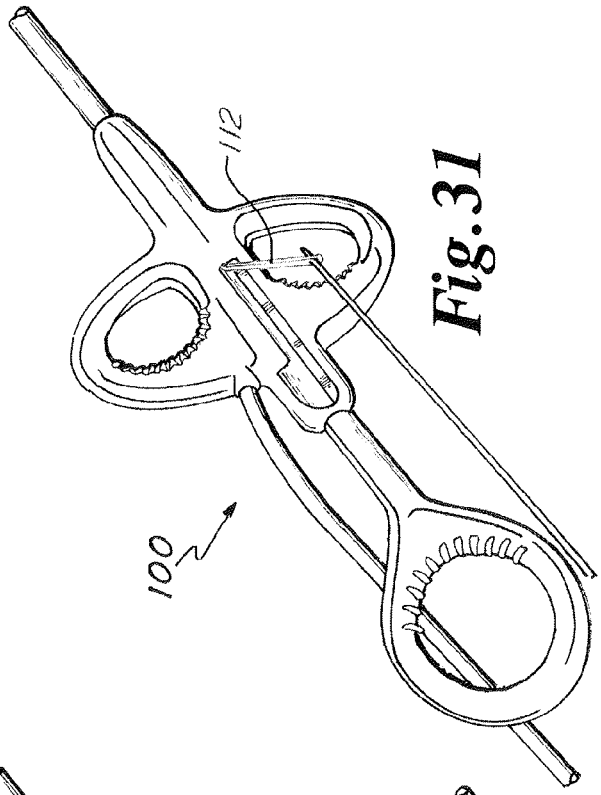

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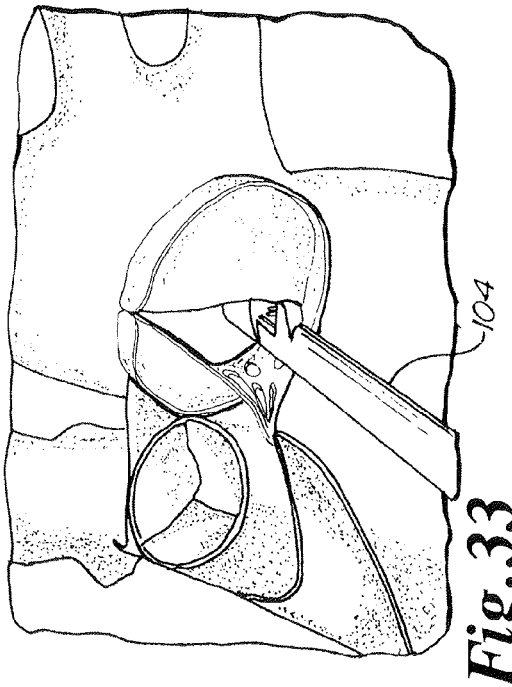

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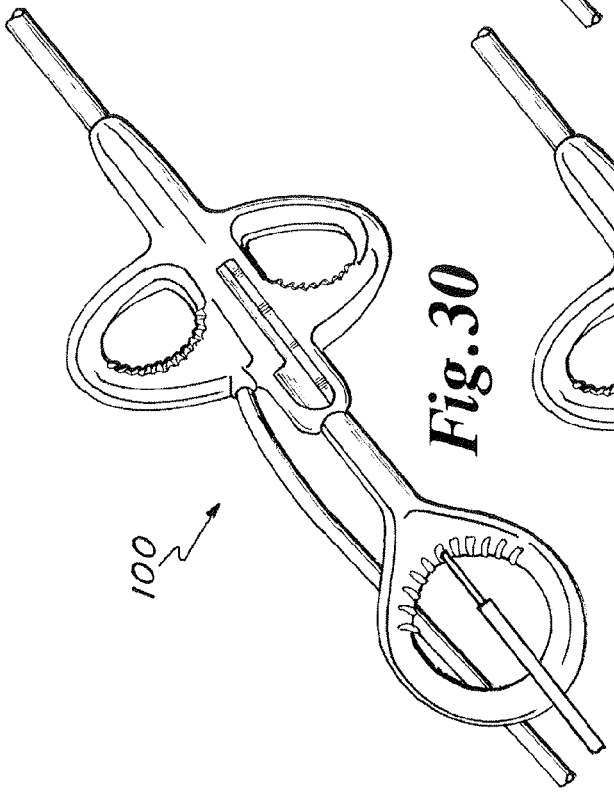

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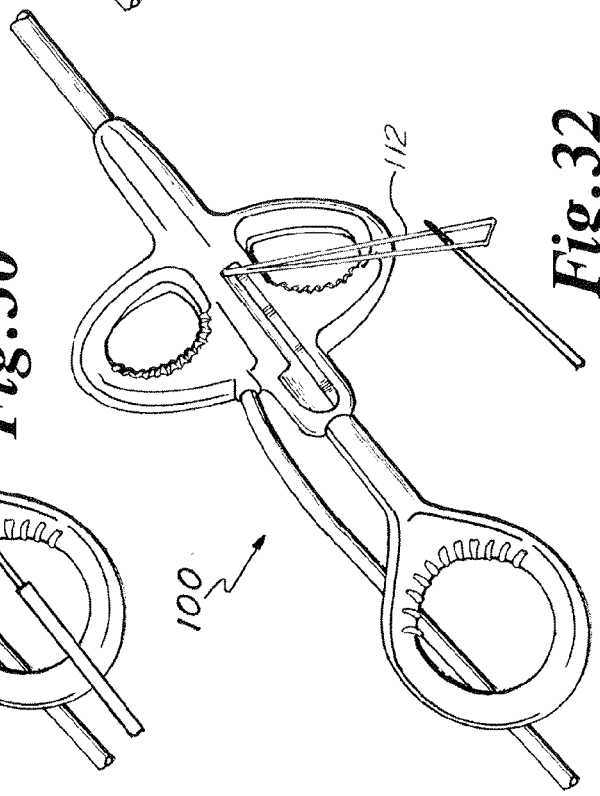

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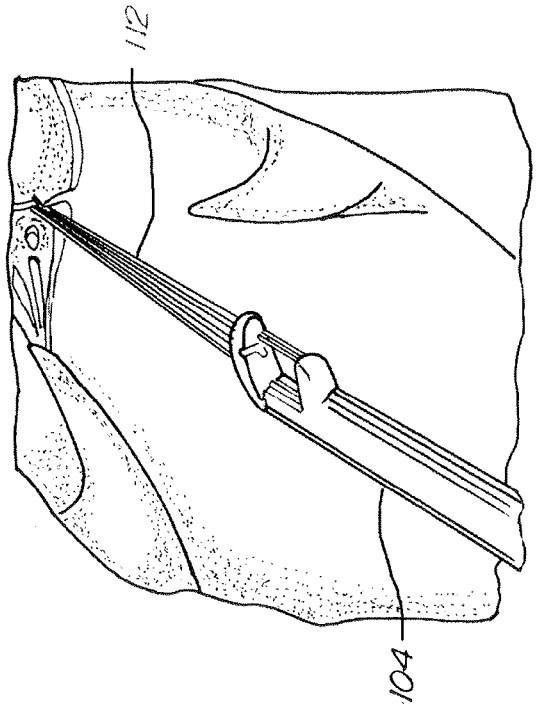

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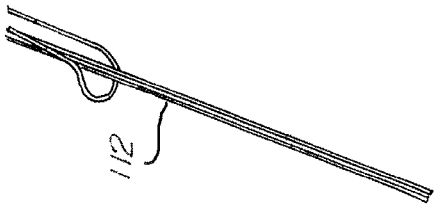

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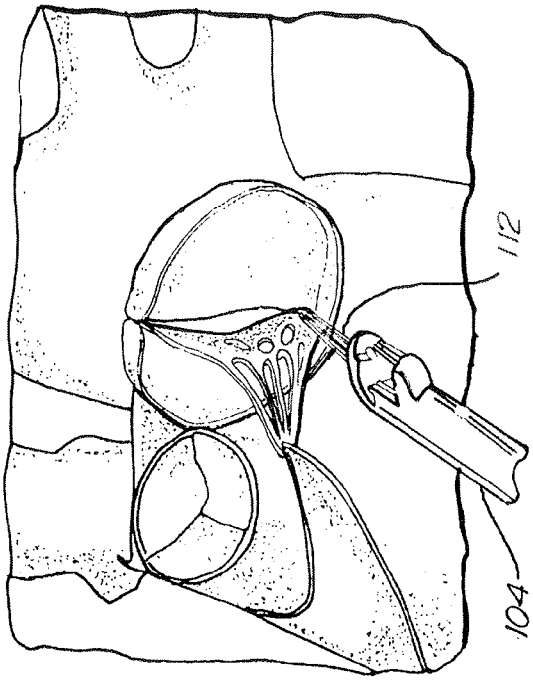

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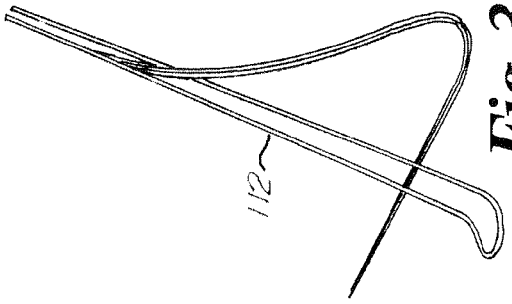

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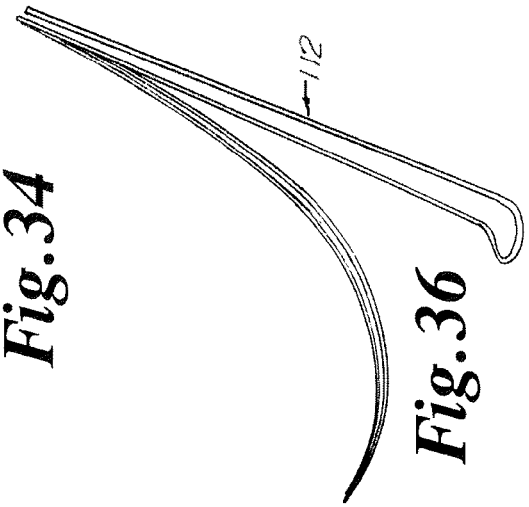

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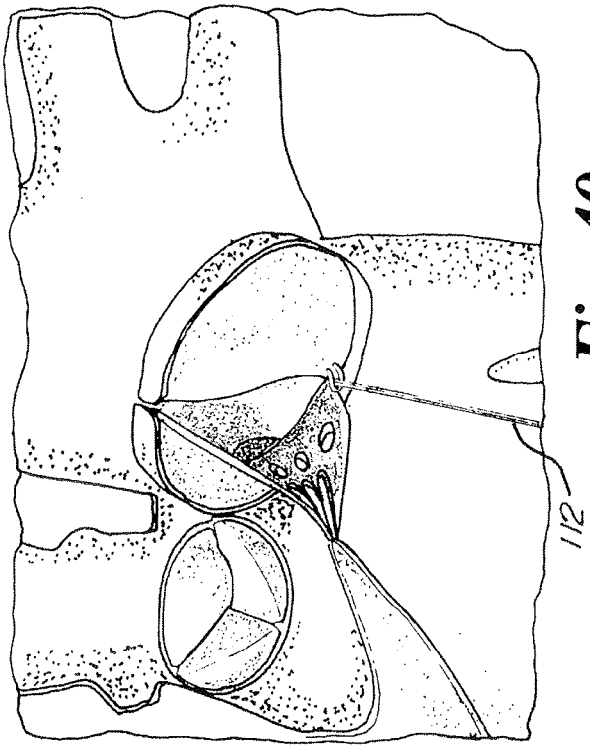

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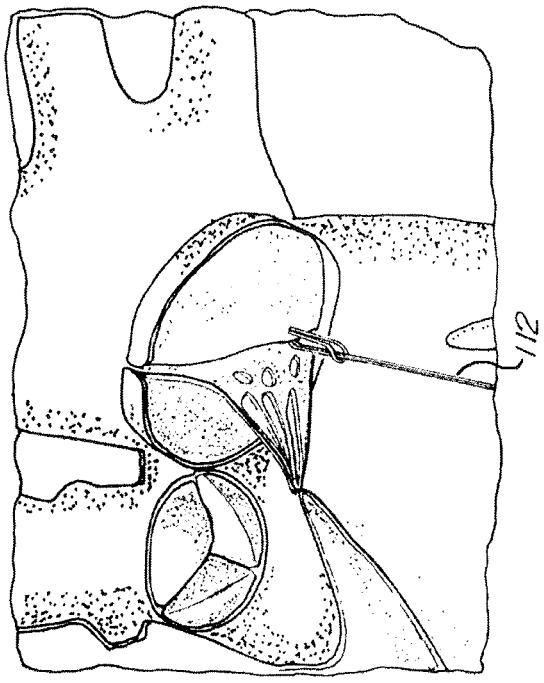

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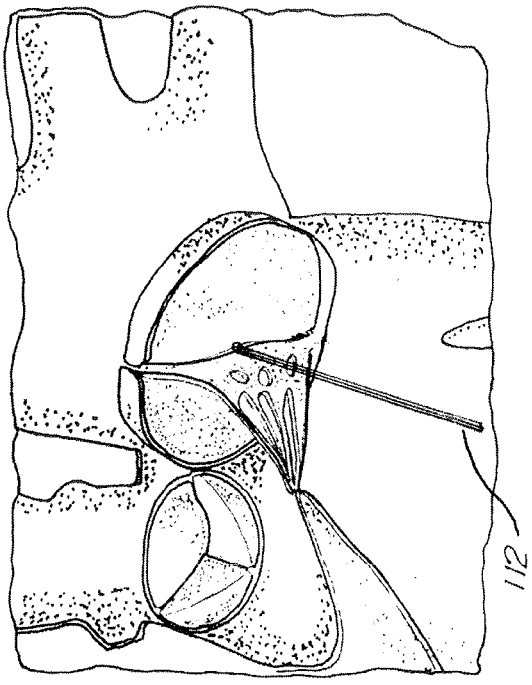

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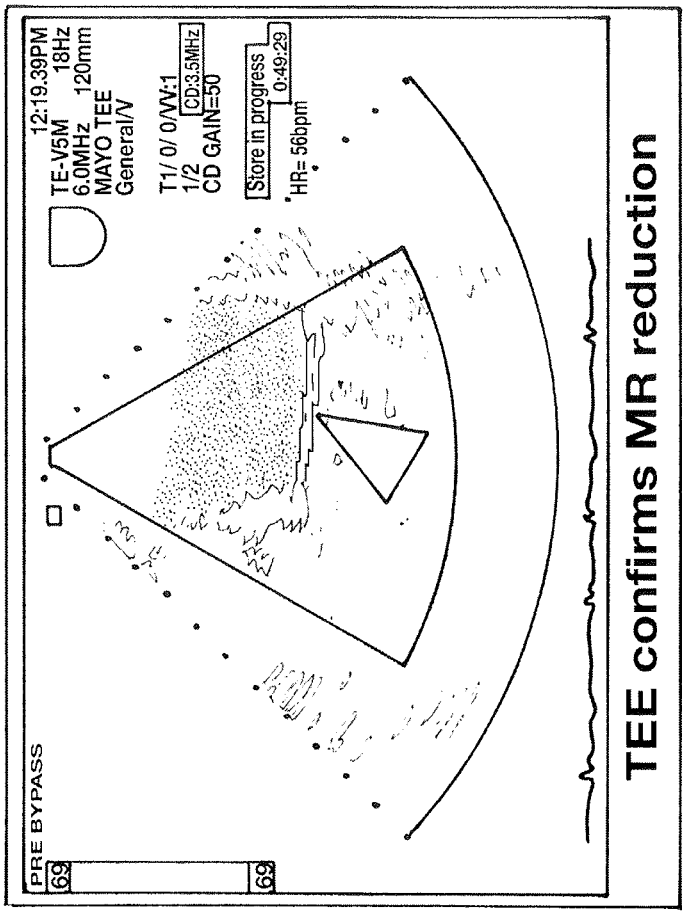

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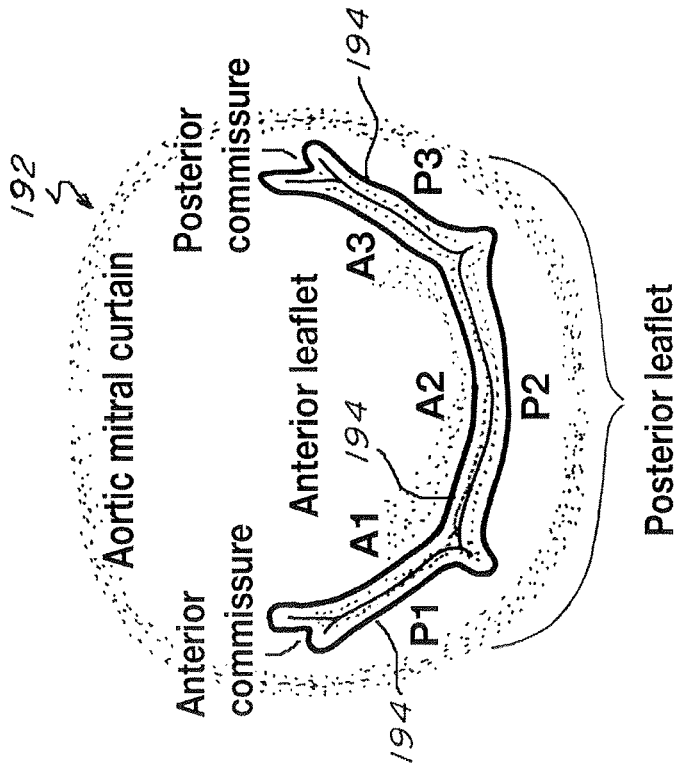

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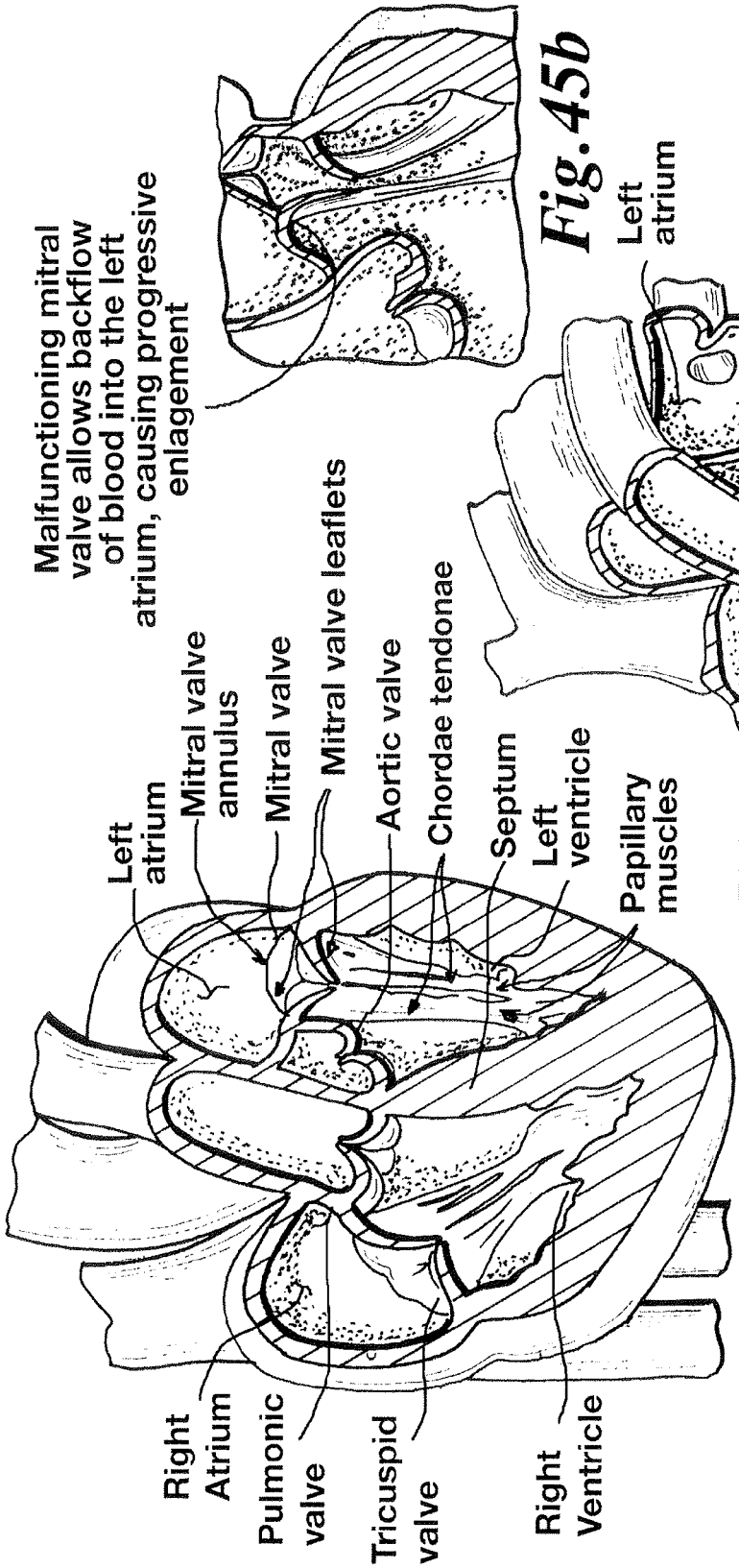

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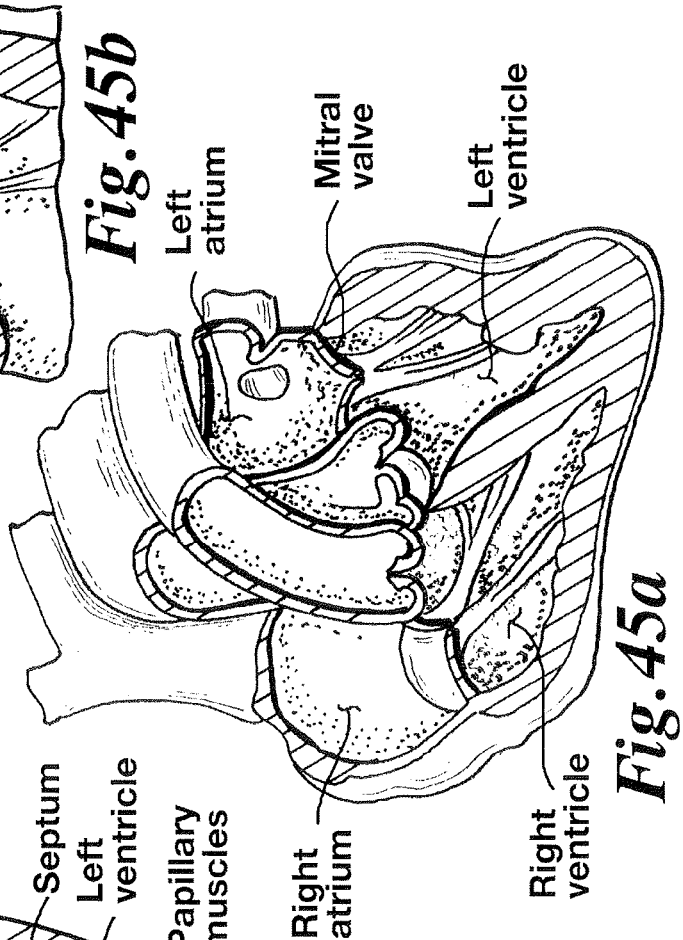

Fig. 45a

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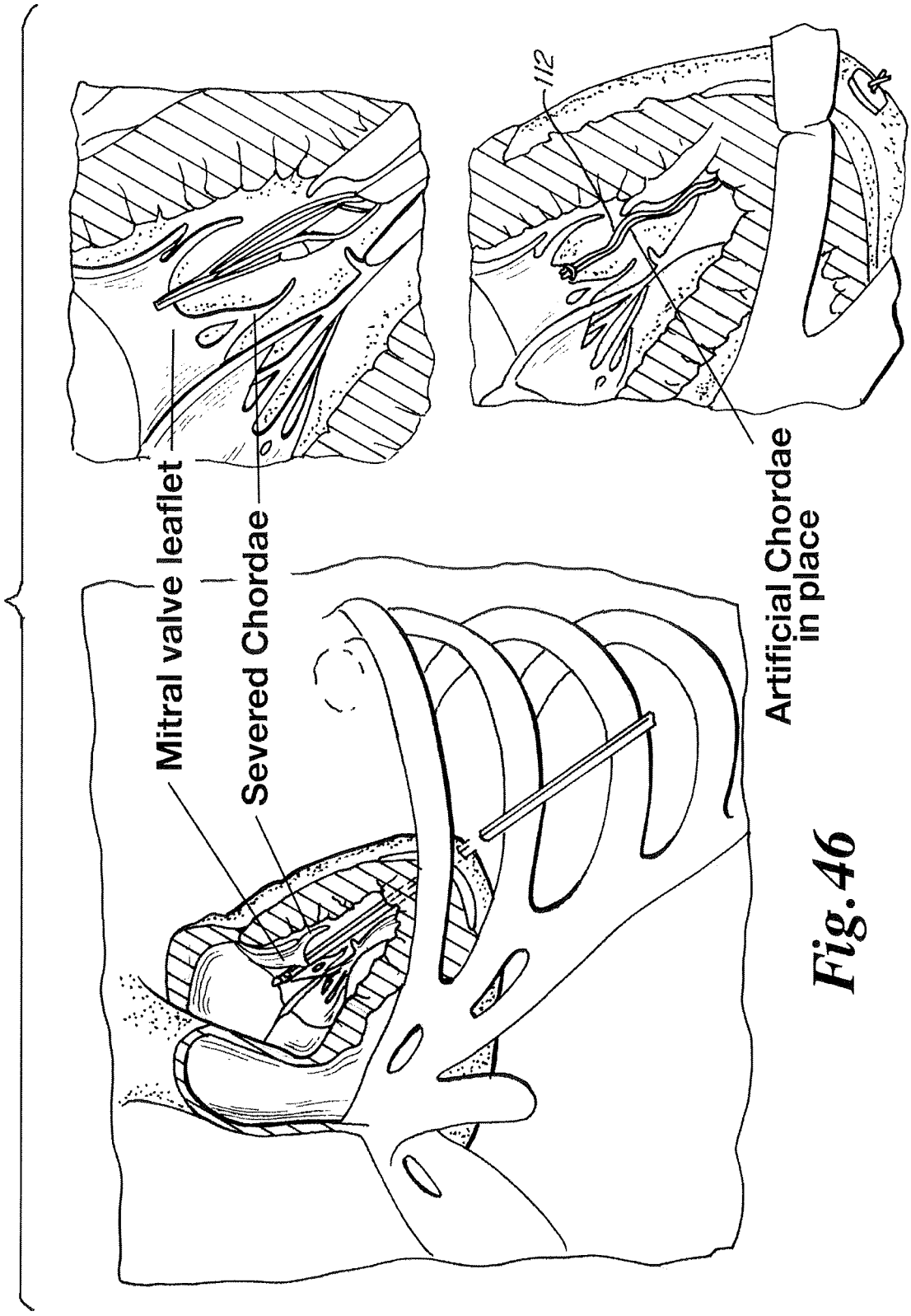
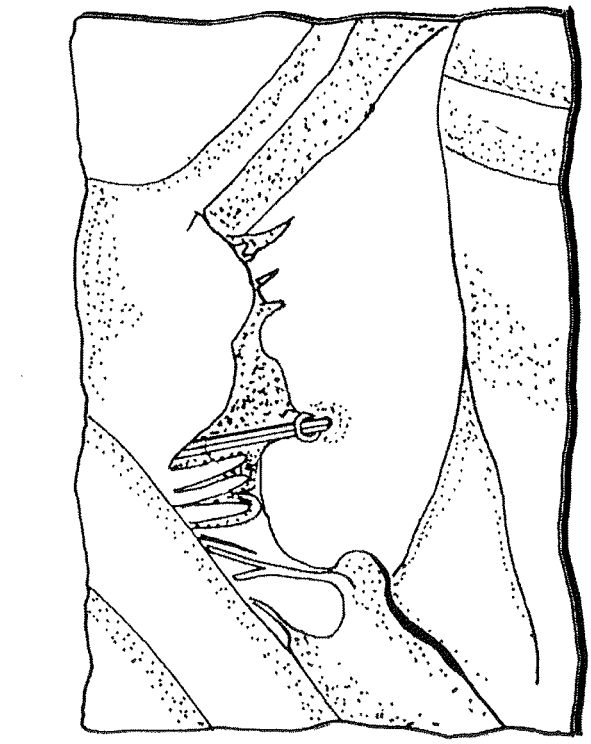
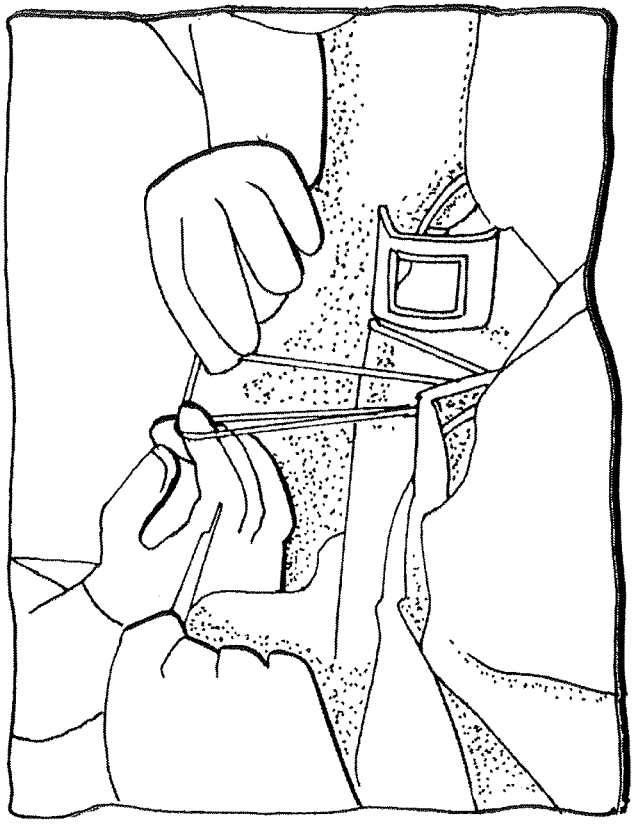

112
Mitral valve leaflet
Severed Chordae
Artificial Chordae
in place

Fig. 46



Suture closure



Surgeon tensions suture

Fig. 47

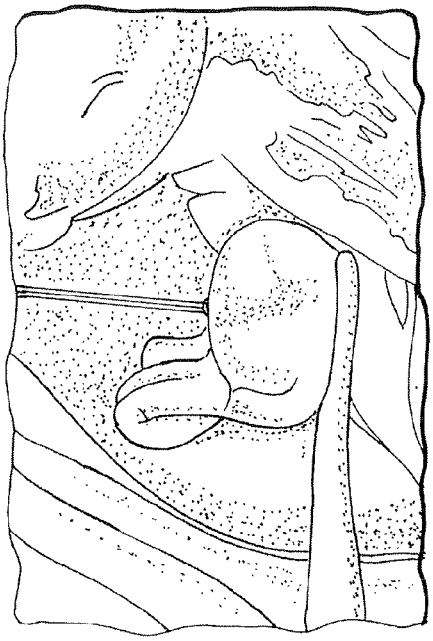


Fig. 48

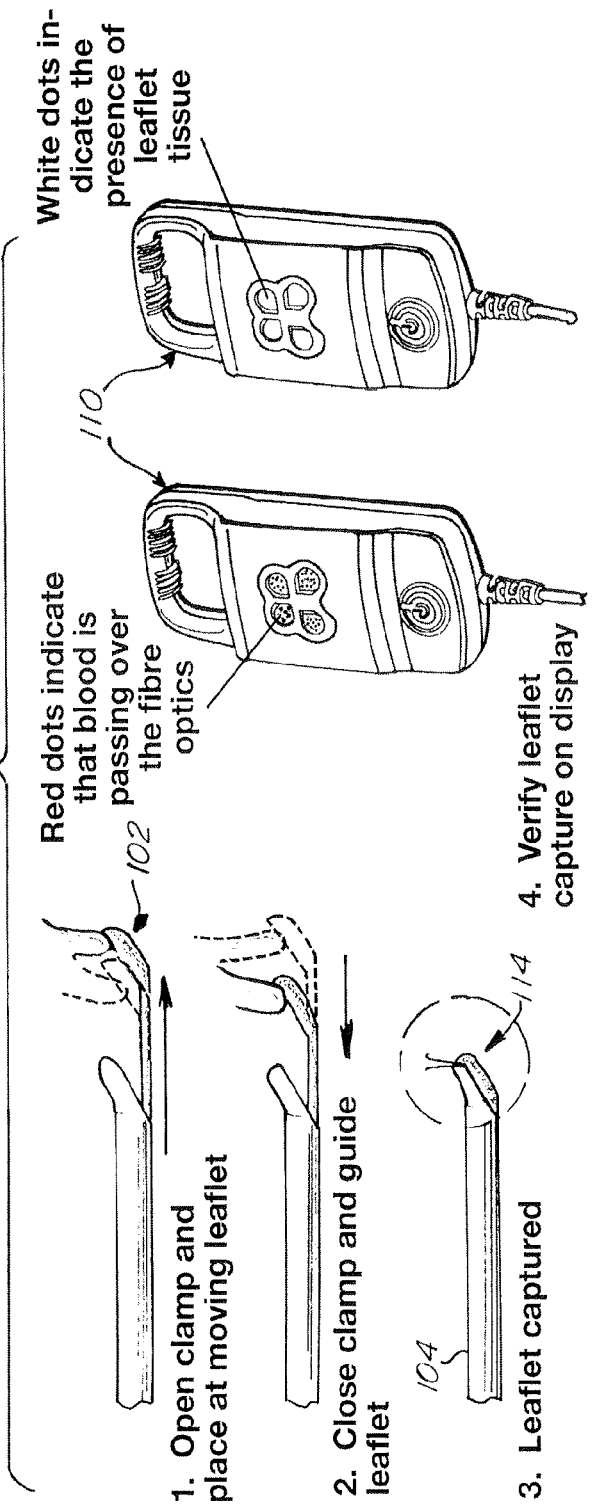

1. Open clamp and place at moving leaflet
2. Close clamp and guide leaflet
3. Leaflet captured
4. Verify leaflet capture on display
Red dots indicate that blood is passing over the fibre optics
White dots indicate the presence of leaflet tissue
102
104
110
114

Fig. 49

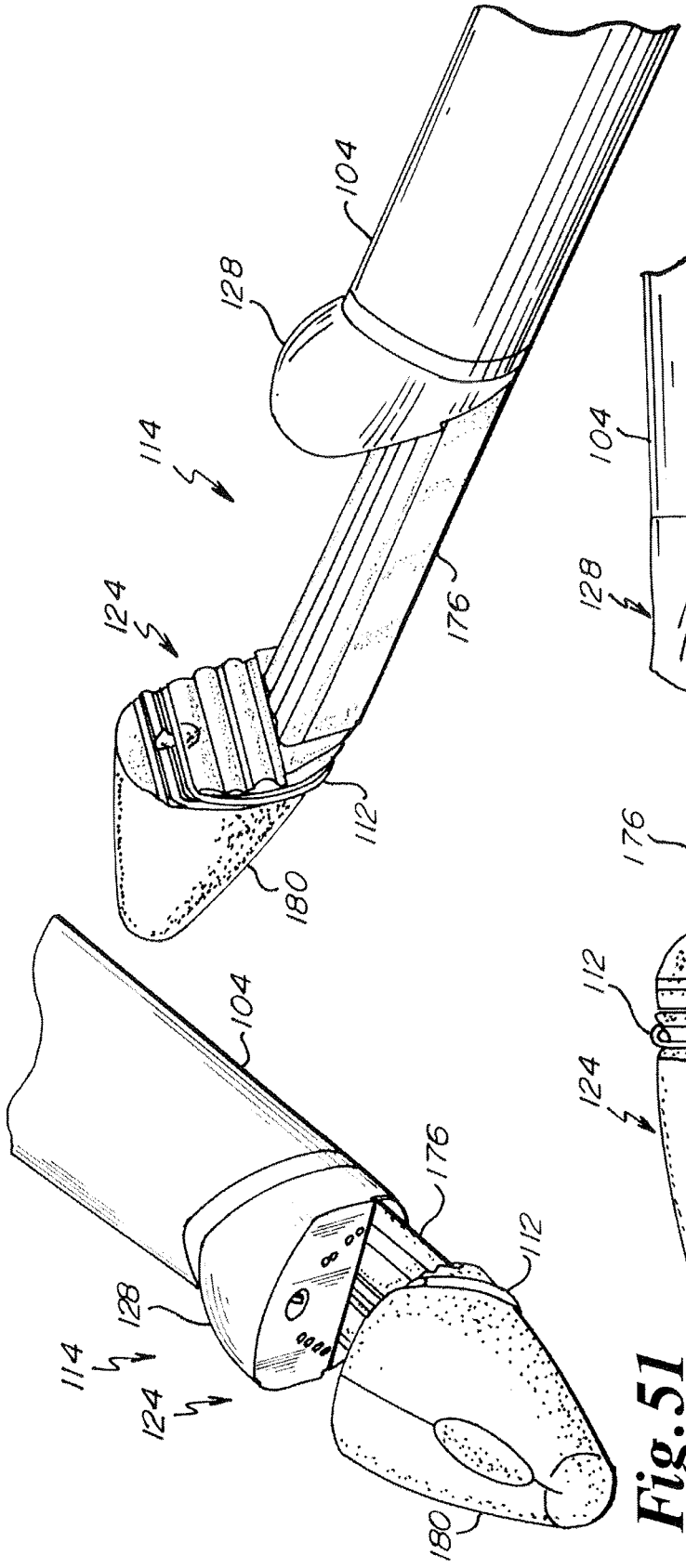


Fig. 50

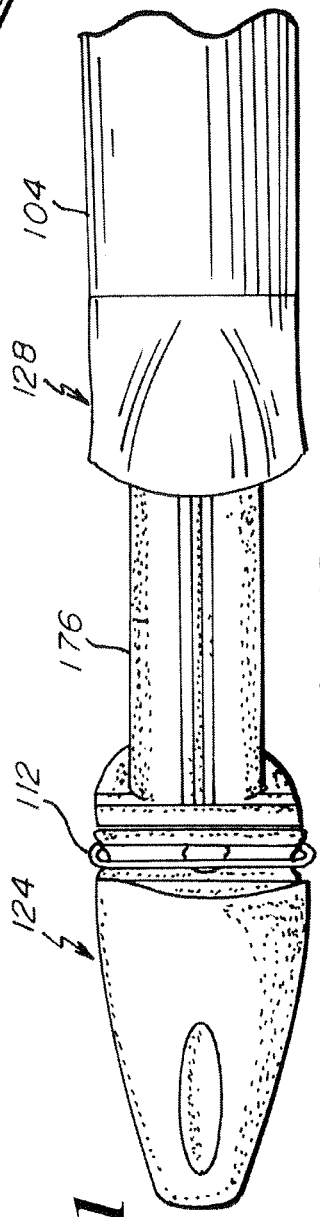


Fig. 52

Fig. 51

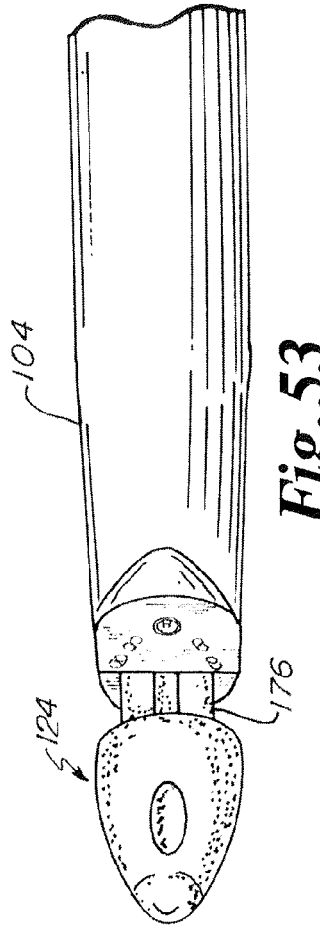


Fig. 53

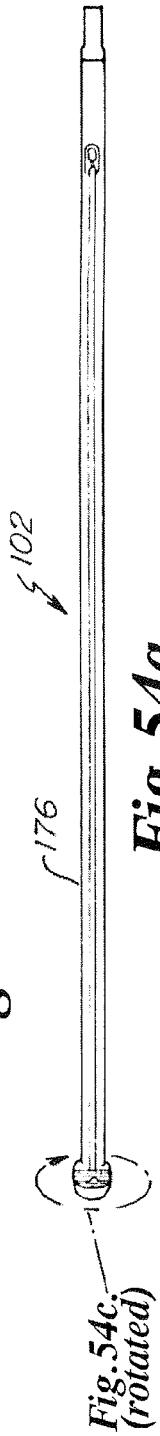


Fig. 54a

Fig. 54c. (rotated)

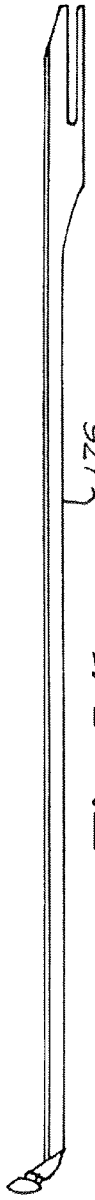


Fig. 54b

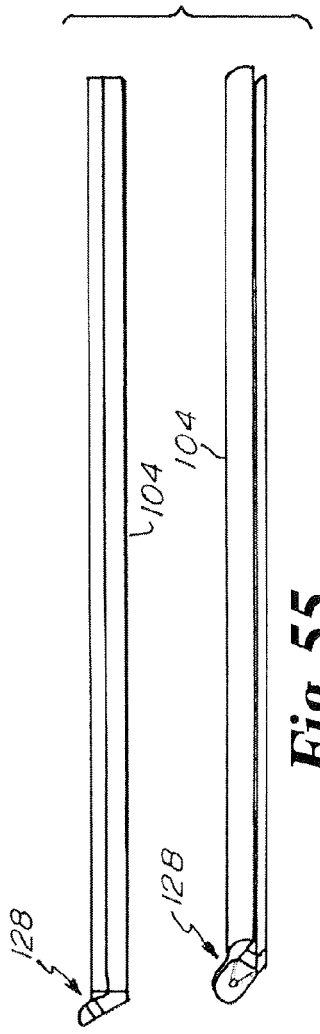


Fig. 55

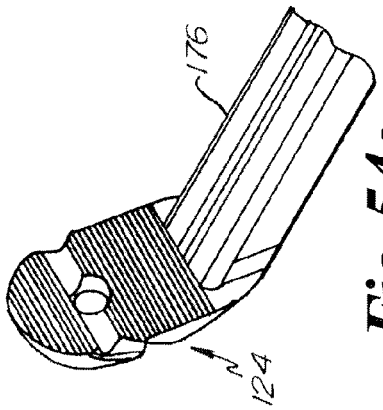


Fig. 54c

MINIMALLY INVASIVE REPAIR OF A VALVE LEAFLET IN A BEATING HEART

RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Application No. 60/999,431, filed Oct. 18, 2007, U.S. Provisional Application No. 60/999,635, filed Oct. 19, 2007, and U.S. Provisional Application No. 60/999,873, filed Oct. 22, 2007, which are incorporated herein in their entirety by reference.

FIELD OF THE INVENTION

The present invention relates to minimally invasive delivery of a suture. More particularly, the present invention relates to attaching artificial chordae tendineae to a flailing or prolapsing leaflet in a beating heart.

BACKGROUND OF THE INVENTION

Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed

mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced by excising the valve leaflets of the natural valve and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses.

The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into a position accessible through the sternotomy. An opening, or atriotomy, is then made in the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the aforementioned techniques may then be used to repair or replace the valve.

An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are/is undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening onto the thoracic cavity. The left atrium is then exposed on the posterior side of the heat, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendineae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendineae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle. This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

One alternative to open heart surgery is a robotically guided, thoracoscopically assisted cardiotomy procedure marketed under the tradename of the DaVinci® system. Instead of requiring a sternotomy, the DaVinci® system uses a minimally invasive approach guided by camera visualization and robotic techniques. Unfortunately, the DaVinci®

system is not approved for mitral valve repair procedures on a beating heart. Thus, the use of the DaVinci® system for mitral valve repair still requires a cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

While there are other laparoscopic and minimally invasive surgical techniques and tools that have been developed, none of these devices are useable for the unique requirements of mitral valve repair on a beating heart. Suturing devices like the Superstich™ vascular suturing device or the Gore® suture passer are designed to permit manual placement of sutures as part of a surgical procedure, but are not designed for use on a beating heart. While certain annuloplasty techniques and instruments that can suture an annuloplasty ring as part of vascular repair or heart bypass surgery may be used in conjunction with a beating heart, these annuloplasty procedures do not involve the capture or retention of a constantly moving leaflet. Consequently, the design and use of annuloplasty techniques and instruments are of little help in solving the problems of developing instruments and techniques for minimally invasive thoracoscopic repair of heart valves.

Recently, a technique has been developed for minimally invasive thoracoscopic repair of heart valves while the heart is still beating. Int'l Pub. No. WO 2006/078694 A2 to Speziali discloses a thoracoscopic heart valve repair method and apparatus. Instead of requiring open heart surgery on a stopped heart, the thorascopic heart valve repair methods and apparatus taught by Speziali utilize fiber optic technology in conjunction with transesophageal echocardiography (TEE) as a visualization technique during a minimally invasive surgical procedure that can be utilized on a beating heart. U.S. Publication No. 2008/0228223 to Alkhatib also discloses a similar apparatus for attaching a prosthetic tether between a leaflet of a patient's heart valve and another portion of the patient's heart to help prevent prolapse of the leaflet and/or to otherwise improve leaflet function.

While the Speziali invention represents a significant advance over open heart techniques for heart valve repair, it would be advantageous to further improve upon this new technique.

SUMMARY OF THE INVENTION

Embodiments of the present invention are generally directed to apparatus and methods for minimally invasive surgical procedures. Although embodiments of the present invention disclosed herein may be adapted or used for any number of purposes, the present invention can generally be used to repair mitral valve leaflets by delivering an implanting one or more sutures to function as artificial chordae tenindae.

In an embodiment of the invention, a valve repair device with a replaceable suture cartridge for repair of a valve leaflet in a beating heart of a patient comprises a valve repair device and a replaceable suture cartridge. The valve repair device includes a main shaft, a handle, a capture assembly, and a needle head. The main shaft has a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient. The handle has an actuator operably connected to the proximal end of the main shaft. The capture assembly is operably coupled to the distal end of the main shaft and includes one portion of a jaw assembly adapted to grasp the valve leaflet in response to selective actuation of the actuator. The needle head is slidably positionable within the capture assembly to penetrate the valve leaflet. The replaceable suture cartridge includes a secondary shaft having a distal portion and a proximal portion. The distal portion includes a second portion of the jaw assembly integrally couplable to the capture assembly. The proximal portion is releasably couplable to the handle and the actuator. The secondary shaft is adapted to slidingly engage structure defined along the main shaft such that the actuator is actuatable to selectively position the second portion of the jaw assembly along a longitudinal axis the capture assembly. The replaceable suture cartridge includes structure defining a channel within which a suture is carried, the suture having a loop portion presented proximate the jaw assembly when the replaceable suture cartridge is engaged with the valve repair device.

In further embodiments, the replaceable suture cartridge further may include a means for retaining the suture. The secondary shaft may define a proximally located suture channel adapted to receive the suture and the replaceable suture cartridge may further include a biasing member adapted forceably retain a portion of the suture within the suture channel. The needle head may be slidably positionable within the channel to engage the suture at a fully extended position. The suture retention system may be adapted to release the suture from the biasing member when the needle head reaches the fully extended position. The handle may include a release button and the replaceable suture cartridge may be configured such that actuation of the release button causes the secondary shaft to disengage from the handle. The loop portion of the suture may be adapted for the formation of a girth knot or an Alfieri stitch. The distal portion of the secondary shaft may include a first channel adapted to receive the loop portion and a second channel adapted to receive the needle head when actuated to an extended position. The second channel may interface with the first channel to present the loop portion to the needle head in the extended position.

In an embodiment, a plurality of the replaceable suture cartridges and the valve repair device may be provided together as a kit.

In an embodiment, a method includes using any of the embodiments of the valve repair device and the replaceable suture cartridge as described heretofore as part of a valve repair operation.

In an embodiment, a method includes providing any of the embodiments of the valve repair device and the replaceable suture cartridges as described heretofore and providing instructions for using the replaceable suture cartridge together with the valve repair device to perform a valve repair operation.

In further embodiments, the device can be used in conjunction with external transesophageal echocardiography (TEE) to visualize a valve leaflet to verify leaflet capture. In various embodiments, the device can provide assistance in performing repair of heart valves through a midline sternotomy during cardiopulmonary by-pass thoracotomy modalities, including anterolateral thoracotomy, in addition to minimally invasive procedures.

Throughout the specification, any references to such relative terms as top and bottom, and the like are intended for convenience of description and are not intended to limit the present invention or its components to any one positional or spatial orientation. It will be further understood that various dimensions of the components in the attached figures may vary depending upon specific applications and intended use of the invention without departing from the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The embodiments of the present invention may be more completely understood in consideration of the following

detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. **1**A is a perspective view of a device for delivering and manipulating a suture in a beating heart, according to an embodiment of the present invention;

FIG. **1**B is a perspective view of a device for delivering and manipulating a suture in a beating heart, according to an embodiment of the present invention.

FIG. **2** is a front/top perspective view of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **3** is a front/top perspective view of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **4**A is a front/top perspective view of the distal tip of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **4**B is a front/top perspective view of the distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**C is a side elevation view of the distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**D is a rear/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**E is a front/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**F is a front/bottom perspective view of the upper clamp jaw and shaft of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**G is a front/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**H is a side elevation view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**I is a rear/top perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **4**J is a rear/top perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **5** is a front/top perspective view of the pre-loaded suture cartridge depicted in FIG. **2**;

FIG. **5**A (view A cartridge in phantom) is a front/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. **5**C (view A, rotated, cartridge in phantom) is a rear/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. **5**D (view A, rotated) is a rear/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. **5**B (view B) is a front/top perspective view of the proximal end of a pre-loaded suture cartridge;

FIG. **5**E (view B, cartridge in phantom) is a front/top perspective view of the proximal end of a pre-loaded suture cartridge;

FIG. **6** is a front/top perspective view of the operating room loaded cartridge depicted in FIG. **3**;

FIG. **6**A (rotated) is a rear/top perspective view of the distal end of a operating room loaded cartridge;

FIG. **7** is a front/top perspective view of the needle assembly depicted in FIG. **1**A;

FIG. **7**A is a front/top perspective view of the distal end of a needle assembly;

FIG. **8** is a rear/top perspective view of an extended needle within the open distal tip of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **8**A is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A with the needle assembly in the start position;

FIG. **8**B is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A with the needle assembly in the start position;

FIG. **8**C is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A with the needle assembly in the fully advanced position;

FIG. **8**D is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A with a retracted needle assembly;

FIG. **9** is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A (with certain parts omitted for clarity);

FIG. **10** is a rear/bottom perspective view of the proximal end of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **11** is a front/top perspective view of the plunger assembly depicted in FIG. **8**A;

FIG. **12** is a front/top perspective view depicting fiber optic cable assembly depicted in FIG. **1**A and leaflet capture verification monitor depicted in FIG. **1**A;

FIG. **13** is an exploded front/top perspective view of the fiber optic cable assembly depicted in FIG. **12**;

FIG. **14** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **15** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **16** is a front/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **17** is a front perspective view of the leaflet capture verification monitor depicted in FIG. **1**A;

FIG. **18** is a front perspective view of the leaflet capture verification monitor depicted in FIG. A;

FIG. **19** is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **20** is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A;

FIG. **21** is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **22** is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **23** is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **24** is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **25** is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **26** is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **27** is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. **1**A, with the clamp shown in phantom;

FIG. **28** is a top/rear perspective view of the handheld suture deployment device depicted in FIG. A;

FIG. **29** is a top/rear perspective view of the handheld suture deployment device depicted in FIG. A;

FIG. **30** is a top/rear perspective view of the handheld suture deployment device depicted in FIG. **1**A and the needle assembly depicted in FIG. **1**A partially retracted from the handheld suture deployment device;

FIG. **31** is a top/rear perspective view of the handheld suture deployment device depicted in FIG. **1**A, the needle assembly depicted in FIG. **1**A retracted from the handheld suture deployment device, and the suture depicted in FIG. **1**A;

FIG. **32** is a top/rear perspective view of the handheld suture deployment device depicted in FIG. **1**A, the needle assembly depicted in FIG. **1**A retracted from the handheld suture deployment device, and the suture depicted in FIG. **1**A;

FIG. **33** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. **1**A partially retracted from the heart chamber;

FIG. **34** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. **1**A partially retracted from the heart chamber;

FIG. **35** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. **1**A partially retracted from the heart chamber;

FIG. **36** is an perspective view of the loop and non-loop ends of the suture depicted in FIG. A;

FIG. **37** is an perspective view of the loop and non-loop ends of the suture depicted in FIG. A;

FIG. **38** is an perspective view of the loop and non-loop ends of the suture depicted in FIG. A;

FIG. **39** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and a loose girth hitch on the leaflet;

FIG. **40** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and a loose girth hitch on the leaflet;

FIG. **41** is a front/bottom perspective view of a mitral valve leaflet in need of repair, and an adjusted girth hitch on the leaflet;

FIG. **42** is screen capture of the display of an external transesophageal echocardiography showing a reduction in MR;

FIG. **43** is a schematic top plan view of a mitral valve;

FIG. **44** is a cross-sectional view of a heart;

FIG. **45**A is a cross-sectional view of a heart with a normal mitral valve;

FIG. **45**B is a partial cross-sectional view of a heart with an abnormal mitral valve;

FIG. **46** is an perspective partial cut-away front view of apical access of a heart with insets showing the mitral valve leaflets and chordae tendonae;

FIG. **47** is a view of a surgeon tensioning a suture and of a suture securing a leaflet;

FIG. **48** is a view of a suture securing a leaflet;

FIG. **49** is a series of side elevation views of the open distal tip of the handheld suture deployment device depicted in FIG. **2** capturing a leaflet, and two front perspective views of the leaflet capture verification monitor depicted in FIG. **1**A;

FIG. **50** is a top/rear perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **51** is a top/front perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **52** is a top plan view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**;

FIG. **53** is a front perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. **2**.

FIG. **54** is a top plan view and a side elevation view of the suture cartridge depicted in FIG. **1**A; and

FIG. **55** is a side elevation view and a front/bottom perspective view of the shaft depicted in FIG. **1**A.

While the present invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the present invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Certain embodiments of the present invention are directed to apparatus, systems and methods for performing thoracotomy modalities to repair heart valves in either a beating heart or a heart during cardiopulmonary by-pass; or thoracoscopic repair of heart valves in a beating heart. A device that can be used for these purposes is depicted generally with reference numeral **100**.

Although the methods and apparatuses of the present invention can be used for any number of treatments requiring the delivery and manipulation of a suture, the present invention, according to certain embodiments, is generally intended for use in treating a heart condition known as mitral valve regurgitation (MR). Mitral valve regurgitation, which is also commonly referred to as mitral insufficiency or mitral incompetence, is a condition characterized by failure of the mitral valve to close properly. When the mitral valve does not close tightly, blood is allowed to flow backward in relation to its normal flow path within the heart. As many as one in five people over fifty-five years of age have some degree of mitral valve regurgitation.

As depicted in FIGS. **44-45**, the heart has four chambers. The two upper chambers, called the left and right atria, receive blood. The two lower chambers, called the left and right ventricles, pump blood. Four valves aid in directing blood flow through the heart's chambers. These heart valves open and close, allowing blood to flow in only one direction.

A mitral valve is depicted illustratively in FIGS. **43-45**. Situated between the left atrium and left ventricle, the mitral valve consists of two flaps of tissue, or leaflets. The mitral valve annulus forms a ring around the valve leaflets, thereby connecting the leaflets to the heart muscle. Papillary muscles are located at the base of the left ventricle. Anchoring the mitral valve leaflets to the papillary muscles are tendon-like cords called chordae tendineae. Normal chordae tendineae prevent the leaflets from prolapsing, or inverting, into the left atrium, as depicted in FIG. **45**A.

Under normal cardiac conditions, the left atrium contracts and forces blood through the mitral valve and into the left ventricle. As the left ventricle contracts, hemodynamic pressure forces the mitral valve shut and blood is pumped through the aortic valve into the aorta. For the mitral valve to shut properly, the valvular edges of the valve leaflets must form a non-prolapsing seal that prevents the backflow of blood during left ventricular contraction.

A properly functioning mitral valve opens and closes fully. When the mitral valve fails to fully close, as depicted in FIG. **45**B, blood from the left ventricle is able to flow backward into the left atrium instead of flowing forward into the aorta. This backflow of blood through the heart valve is called regurgitation. The regurgitation of blood through the heart

due to the failure of the mitral valve to close properly is the condition known as mitral valve regurgitation. A common symptom of mitral valve regurgitation is congestion of blood within the lungs.

When blood regurgitates from the left ventricle into the left atrium, such as due to MR, less blood is pumped into the aorta and throughout the body. In an attempt to pump adequate blood to meet the blood needs of the body, the left ventricle tends to increase in size over time to compensate for this reduced blood flow. Ventricular enlargement, in turn, often leads to compromised contractions of the heart, however, thereby exacerbating the congestion of blood within the lungs. If left untreated, severe MR can eventually lead to serious cardiac arrhythmia and/or congestive heart failure (CHF).

Mitral valve regurgitation can be caused by any number of conditions, including mitral valve prolapse (a condition in which the leaflets and chordae tendineae of the mitral valve are weakened resulting in prolapse of the valve leaflets, improper closure of the mitral valve, and the backflow of blood within the heart with each contraction of the left ventricle), damaged chords (wherein the chordae tendineae become stretched or ruptured, causing substantial leakage through the mitral valve), rheumatic fever (the infection can cause the valve leaflets to thicken, limiting the valve's ability to open, or cause scarring of the leaflets, leading to regurgitation), endocarditis (an infection inside the heart), deterioration of the mitral valve with age, prior heart attack (causing damage to the area of the heart muscle that supports the mitral valve), and a variety of congenital heart defects. Normally, mitral valve regurgitation does not pose a serious health threat. As MR becomes exacerbated over time, however, the condition can become more severe, resulting in life-threatening complications, including atrial fibrillation (an irregular heart rhythm in which the atria beat chaotically and rapidly, causing blood clots to develop and break loose and potentially result in a stroke), heart arrhythmias, and congestive heart failure (occurring when the heart becomes unable to pump sufficient blood to meet the body's needs due to the strain on the right side of the heart caused by fluid and pressure build-up in the lungs).

According to certain embodiments, the present invention generally reduces the need to treat mitral valve regurgitation in most individuals with a sternotomy and cardiopulmonary bypass surgery. Specifically, the present invention can provide a minimally invasive treatment of MR. This treatment significantly decreases trauma to surgical patients by facilitating transapical access of a beating heart via a lateral thoracotomy, as depicted in FIG. **46**, in a manner that eliminates certain surgical steps normally required to complete mitral valve repair procedure by sternotomy.

Transapical access to a heart includes all entry points that are within approximately the bottom third of the heart. As used in this patent application, transapical access to a heart includes all directions of entry and points of entry, as well as all angles of entry at each entry point.

According to certain embodiments, the present invention is compatible with, and directed to percutaneous access to the heart. According to other embodiments, the present invention is compatible with, and directed to other access points to a heart.

Referring to FIG. **1**B, device **100** may include handle assembly **300**, capture assembly **302**, and needle **138** according to an embodiment of the present invention. Handle assembly **300** generally has distal end **304** and proximal end **306**. Handle assembly includes shaft **308** and actuator **309**. Shaft **308** extends from distal end **304** of handle assembly **300** and is generally adapted to be extended into the chest cavity of a patient. Actuator **309** is positioned proximate proximal end **306**. Capture assembly **302** generally has distal portion **310** and proximal portion **312**. Distal portion **310** includes clamping mechanism **314** formed by first clamping jaw **316** and second clamping jaw **318**. In an embodiment, clamping mechanism **314** is adapted to grasp and release a valve leaflet. In a further embodiment, first clamping jaw **316** or second clamping jaw **318** is selectively positionable along a longitudinal axis of capture assembly **302** in response to actuation of actuator mechanism **314** to create a space between the interior surfaces (not shown) of the first and second clamping jaws **316**, **318**.

Referring to FIG. **1**A, device **100** can deliver and manipulate a suture in a beating heart and generally includes a handheld suture deployment device **118**, and capture confirmation system **101**, according to an embodiment of the invention. The handheld suture deployment device **118** generally includes a suture cartridge **102**, a shaft **104**, a handle **106**, and a needle assembly **116**. Capture confirmation system **101** generally includes fiber optic cable assembly **108**, and leaflet capture verification (LCV) monitor **110**. Although device **100** can be used for any number of purposes without departing from the spirit or scope of the present invention, the aforementioned platform of components, as is described hereinafter in further detail, enable the extending of a shaft through the chest cavity and into a beating heart chamber to capture a valve leaflet of a valve needing repair, and to further provide a needle to operably penetrate the captured valve leaflet and draw a suture therethrough

Suture cartridge **102** may be pre-loaded suture cartridge **120** or operating room-loaded cartridges **122**. Referring to FIG. **5**, pre-loaded suture cartridge **120** can include a tapered lower clamp jaw **124**, a suture **112**, a suture retention system **130**, a handle interface **174**, a channel **131**, and a groove on the clamp surface **162***a*. Suture cartridge **120** has proximal **198** and distal **196** ends. The lower clamp jaw **124** is located at the distal end **196** of suture cartridge **120**. The handle interface **174** is located at the proximal end **198** of suture cartridge **120**. Channel **131** is provided with a pair of openings, a first opening which is located on the top surface, and a second opening which is located on the bottom surface of suture cartridge **120**. Channel **131** runs vertically through suture cartridge **120**, and is located near the proximal end **198** of suture cartridge **120**, such that channel **131** and handle interface **174** are located generally adjacent to one another. Intermediate channel **131** and lower clamp jaw **124** is a cartridge shaft **176**.

Referring to FIGS. **4**A-**4**E, **4**G-**4**J and FIG. **5**, lower clamp jaw, or distal tip portion, **124** is provided on the distal end of suture cartridge **120** according to an embodiment of the invention. For example, lower clamp jaw **124** and upper clamp jaw **128** may work cooperatively to form a low profile, tapered tip grasping device. Lower clamp jaw **124** generally includes a low profile tip **180**, a lumen **182**, a groove **162**, a lower clamp surface **126** and two channels **163**. Lumen **182** extends from the distal end to the proximal end of lower clamp jaw **124**, parallel to the axis of cartridge shaft **176**. Lumen **182** can be substantially straight, with an inner diameter adapted to receive needle end **146**. Groove **162** can be either groove **162***a* or groove **162***b*.

According to an embodiment of this invention, groove **162***a* is disposed on lower clamp surface **126**, and is located laterally along surface **126**, as depicted in FIG. **4**D. The depth and width of groove **162***a* is generally equal to, or greater than, the diameter of suture **112**.

According to an embodiment, groove **162***b* is disposed on the upper surface of lower clamp surface **126**, as depicted in FIGS. **4**G-**4**J. The depth and width of groove **162***b* is generally equal to, or greater than, the diameter of suture **112**. For embodiment of this invention where groove **162** is groove **162***b*, cutout **161** is provided, as depicted in FIGS. **4**G, **4**I, and **4**J. Cutout **161** is generally a groove that is parallel with, and has a width that is generally at least equal to the diameter of lumen **182**. The distal end of cutout **161** joins with groove **162***b* and the proximal end extends to surface **126**. The depth of cutout **161** extends from the surface of lower clamp jaw **124** to the centerline of lumen **182**.

According to an embodiment, a lower clamp surface **126** is defined by the generally planar canted surface of lower clamp jaw **124**. Clamping plane **129** is the planar distal face of upper clamp jaw **128**. Clamp **114** is in a closed position when lower clamp surface **126** contacts clamping plane **129**. Lower clamp surface **126** has a surface finish generally suitable for retaining a grasped valve leaflet. Suitable surface finishes include a striated or textured surface finish. As depicted in FIGS. **4**D, **4**I-**4**J, and **5**, a suitable surface finish may include a series of groves and ridges.

According to an embodiment, the proximal opening of lumen **182** is located to intersect groove **162***a*, as depicted in FIG. **4**D and view A of FIG. **5**. According to another embodiment, the proximal opening of lumen **182** is located to intersect groove **162***b*, as depicted in FIGS. **4**I and **4**J.

According to an embodiment, the low profile tip **180** is generally smooth in shape and surface finish, and is generally free of sharp edges or points. The low profile tip **180** is sufficiently large so that when needle assembly **116** is in a fully extended position, needle end **146** does not protrude from the distal opening of lumen **182**.

According to an embodiment, cartridge shaft **176** is provided with a cross-sectional profile that is compatible to be slidably retained within cartridge channel **172**. Cartridge shaft **176** is relatively wide, in comparison to the diameter of shaft **104**, as depicted in FIGS. **50**-**53**. In an embodiment, the width of cartridge shaft **176** is approximately 65% of the diameter of shaft **104**. In another embodiment, the width of cartridge shaft **176** is between approximately 65% and approximately 100% of the diameter of shaft **104**. In another embodiment, the width of cartridge shaft **176** is less than approximately 65% of the diameter of shaft **104**. A wide cartridge shaft **176** can prevent body tissue from entering clamp **114** from the bottom and presenting a false capture by capture confirmation system **101**.

According to an embodiment, groove **178** is longitudinally disposed along the centerline of the top surface of shaft **176**. The depth of groove **178** is generally equal to, or greater than, the diameter of suture **112**. The cross-sectional area is generally sufficient to simultaneously encompass the cross-sectional area of two sutures **112**.

According to certain embodiments of this invention, channels **163** are provided along a portion of the proximal surface of lower clamp jaw **124**, as depicted in FIG. **5**A. The depth of channels **163** is generally equal to, or greater than, the diameter of suture **112**. As depicted in FIG. **5**A (view A cartridge in phantom), channels **163** also form a combined cavity that extends generally from the bottom surface of lower clamp jaw **124** to the distal top surface of cartridge shaft **176**. The proximal ends of channels **163** open to groove **178**, and the proximal end of groove **178** opens to channel **131**, thus providing a continuous path for suture **112**.

According to an embodiment of this invention, suture **112** is fed through the suture cartridge **120**, as depicted in FIG. **5**. The length of suture **112** is generally divided into two halves, with the mid-point of the suture length generally located within groove **162***a*. Suture **112** runs along the entire length of groove **162***a* and channels **163**. Suture **112** is also located within groove **178** and channel **131**. The two free ends of suture **112** extend through channel **131**.

The suture retention system **130** may generally include a J-shaped flat spring located near the proximal end of suture cartridge **120**. The straight portion of the "J" is generally parallel with, and located near, the top surface of suture cartridge **120**. The curved portion of the "J" generally descends into channel **131**. The suture retention system **130** is positioned such that the curved portion of the "J" forms an interference fit with the distal wall of channel **131**. The suture retention system **130** acts to retain suture **112** in place within suture cartridge **102** by applying a frictional force on the portion of suture **112** that passes through channel **131**. The frictional force generally acts to retain suture **112** as fed within suture cartridge **102**. Suture retention system **130** can release suture **112** once needle **138** has been advanced to a fully extended position, as depicted in FIG. **8**C.

According to an embodiment, handle interface **174** is located on the proximal end **198** of suture cartridge **120**. Handle interface **174** is provided with suitable structure for being releasably retained within handle **106**. Handle interface **174** may also be provided with suitable structure for being releasably retained within plunger assembly **152**. Suitable structure may include, for example, latches, screws, friction fit attachments, and the like.

As depicted in FIGS. **5**B, **9** and **10**, a cavity located on the lower surface of handle interface **174** is provided. This cavity mates with a catch mechanism located on the lower surface of suture cartridge interface **184**. Thus, handle interface **174** is releasably retained to suture cartridge interface **184**, within the housing of handle **106**, due to the catch mechanism mating with the cavity. Retention of handle interface **174** can be released through operation of release button **160**.

According to an embodiment, operating room loaded cartridges **122** are substantially similar in form fit and function to pre-loaded suture cartridges **120**, except that operating room loaded cartridges **122** are not provided with a suture **112**.

According to certain embodiments of the invention, shaft **104** has a distal end and a proximal end, as depicted in FIG. **1**A. Shaft **104** generally includes lumen **134**, upper clamp jaw **128**, cartridge channel **172** and at least one fiber optic bundle **136**. In one embodiment, shaft **104** includes two or more fiber optic bundles **136**. In an embodiment, shaft **104** includes four fiber optic bundles **136**.

Shaft **104** generally has a diameter that is approximately 6.5 millimeters. The diameter can be greater or less than approximately 6.5 millimeters, however, without departing from the spirit or scope of the present invention. Upper clamp jaw, or proximal tip portion, **128** is located at the distal end of shaft **104**, and handle **106** is located at the proximal end. Referring to FIG. **4**F, cartridge channel **172** defines an opening at the distal end of shaft **104**. Cartridge channel **172** may be a keyed channel that runs for substantially the full length of shaft **104**, and is substantially axially parallel to shaft **104**. As a result of its profile, which generally includes two shoulders, cartridge channel **172** acts to retain suture cartridge **102**.

In one embodiment, shaft **104** generally has a diameter that is less than 12 millimeters. In another embodiment, shaft **104** generally has a diameter that is less than 9 millimeters.

In one embodiment, shaft **104** generally has a tapered region **200** at the distal end of shaft **104** and a substantially

uniform region extending proximally from the tapered region, as depicted in FIG. **1**A. The uniform region being substantially uniformly cylindrical and the tapered region transitioning from a substantially circular end to a substantially oblong end. In one embodiment, tapered region **200** is between approximately one centimeter and ten centimeters in length. In another embodiment, tapered region **200** is between approximately two centimeters and five centimeters in length. In another embodiment, tapered region **200** is between approximately four centimeters and five centimeters in length.

In one embodiment, tapered region **200** has a substantially uniform top-to-bottom height that is between approximately one quarter of one centimeter and two centimeters. In another embodiment, tapered region **200** has a substantially uniform top-to-bottom height that is between approximately one-half-of-one centimeter and one and one-quarter-of-one centimeters. In another embodiment, tapered region **200** has a substantially uniform top-to-bottom height that is approximately 0.81 centimeters.

In one embodiment, the uniform region of shaft **104** has a substantially circular cross-section, and the substantially oblong end of tapered region **200** has a side-to-side width that is less than the diameter of the uniform region. In another embodiment, the side-to-side width of the oblong end of tapered region **200** is approximately between approximately twenty-five millimeters and two and one-half millimeters less than the diameter of the uniform region.

Lumen **134** is substantially axially parallel with both shaft **104** and cartridge channel **172**, according to certain embodiments of the invention. Lumen **134** defines an opening **135** on the planar distal surface of upper clamp jaw **128** and a proximal opening in handle **106**. Lumen **134** is generally substantially straight. The inner diameter of lumen **134** is generally appropriately sized to accommodate needle assembly **116** when inserted alone, and needle assembly **116** when extracted with a captured suture **112**. Lumen **134** is substantially co-axial with lumen **182**

According to certain embodiments of the invention, fiber optic bundles **136** are positioned within shaft **104**. Each fiber optic bundle **136** generally includes two fiber optic strands. Each fiber optic bundle **136** functionally terminated at clamping plane **129**, such that a light input to one of the fiber optic strands results in a reflected, or refracted optical signal that is detectable by the other fiber optic strand within a fiber optic bundle **136**. Such a reflected or refracted optical signal may correspond to the nature and color of any material that is present at, or in proximity to, clamping plane **129**. Fiber optic bundles **136** are operably connected through fiber optic cable assembly **108** to the leaflet capture verification (LCV) monitor **110**.

As depicted in FIGS. **4**A-**4**E and **4**G-**4**J, lower clamp jaw **124** and upper clamp jaw **128** work cooperatively to form clamp, or bifurcated tip, **114**. According to certain embodiments of the invention, clamp **114** which is generally bifurcated, low-profile, and tapered so as to perform any number of grasping functions.

Through the actuation of plunger assembly **152**, lower clamp jaw **124** can be extended distally from upper clamp jaw **128**, and can be retracted. When lower clamp jaw **124** is fully retracted, clamp **114** is in a closed position. In the closed position, lower clamp surface **126** contacts clamping plane **129**. In the closed position, the outer surfaces of upper clamp jaw **128** and the outer surfaces of lower clamp jaw **124** are substantially coextensive. In a closed position, the outside surfaces of lower clamp jaw **124** and upper clamp jaw **128** form a substantially smooth surface such that no snagging, rough or sharp edges or overlaps are formed. When lower clamp jaw **124** is extended, clamp **114** is in an open position. In an open position, lower clamp jaw **124**, and upper clamp jaw **128** can be positioned around a piece of tissue, such as a mitral valve leaflet. Through the relative movement of lower clamp jaw **124**, clamp **114** is operable to capture a valve leaflet, and needle **138** can penetrate the captured valve leaflet via lumens **134**, **182**.

According to certain embodiments of the invention, clamp **114** presents an oversized leaflet capture area compared to the cross-sectional area of shaft **104**.

In a closed position, the outside surfaces of lower clamp jaw **124** and upper clamp jaw **128** form a substantially smooth surface, according to certain embodiments of the invention. This smooth surface can facilitate the insertion of clamp **114** into a tissue opening that is smaller than the clamp's cross-sectional area due to the elasticity of tissue over short periods of time. For the embodiments of the invention depicted in FIGS. **4**A-**4**E and **8**, the shaft diameter is approximately 85% of the maximum diameter of clamp **114**. By employing this ratio of clamp-to-shaft diameters, body tissues can be stretched within their elastic limits, which permits an oversized leaflet capture area within clamp **114** as compared to the cross-sectional area of shaft **104**.

An oversized leaflet capture area, as compared to the shaft's **104** cross-sectional area, is presented due to the clamping angle θ, according to certain embodiments of the invention. Clamping angle θ is the angle that clamping plane **129** makes with a horizontal plane through the centerline of shaft **104** as indicated by θ on FIG. **4**C. For the embodiments of the invention depicted in FIG. **4**C, clamping angle θ is approximately 120 degrees. In other embodiments of the invention, clamping angle θ is approximately between 115 degrees and 125 degrees. In other embodiments of the invention, clamping angle θ is approximately between 90 degrees and 135 degrees. In still other embodiments of the invention, clamping angle θ is approximately between 135 degrees and 155 degrees. A clamping angle that is greater than 90 degrees may result in a leaflet capture area of clamp **114** that is larger, relative to shaft's **104** cross-sectional area, than would be possible were the clamping angle 90 degrees. For a clamping angle that is approximately 120 degrees, the leaflet capture area of clamp **114** will be approximately 30% to 40% larger than if the clamping angle were 90 degrees.

In an embodiment of the present invention, a canted tip with increased clamp travel improves leaflet capture. In another embodiment of the present invention, an exchangeable cartridge improves the simplicity and reliability of suture deployment. In another embodiment of the present invention, a suture deployment and manipulator mechanism is integrated with a visualization and verification system to deploy sutures within a suture zone of a valve leaflet.

According to certain embodiments of the invention, clamp **114** is a low profile tapered tip grasping device. The shape of the tapered tip facilitates leaflet capture by providing a large surface area for leaflet capture, relative to the diameter of the shaft. In one embodiment, the surface area for leaflet capture is between 30% and 50% greater than the cross-sectional area of the shaft **104**. In another embodiment, the surface area for leaflet capture is between 20% and 100% greater than the cross-sectional area of the shaft **104**.

According to certain embodiments of the invention, clamp **114** is a low profile canted tip grasping device. Clamp **114** can be canted in any number of directions. Generally, however, the canted tip is canted up, as depicted in FIGS. **54**-**55**. A large surface area of the canted tip, relative to the diameter of the shaft, facilitates leaflet capture.

A large leaflet capture area can provide a surgeon with certain advantages as compared to a smaller leaflet capture area. These advantages include improved ability to capture a leaflet that may be damaged or enlarged and a leaflet capture that is more stable. Greater stability in turn can provide a surgeon enhanced control of a captured leaflet.

According to an embodiment of the invention, the maximum linear travel of lower clamp jaw **124** in relation to upper clamp jaw **128** is between approximately one and five centimeters.

According to another embodiment of the invention, the maximum linear travel of lower clamp jaw **124** in relation to upper clamp jaw **128** is between approximately two and three centimeters.

According to certain embodiments of the invention, handle **106** is formed to be manipulated by an operator. Operator may be, for example, a surgeon, or the controllable device-interfacing end of a robotic system. In one embodiment, handle **106** is adapted to be grasped by the index and middle finger of a surgeon. Shaft **104** extends from the distal end of handle **106**, and plunger assembly **152** is retained in the proximal end. As depicted in FIG. **9**, structure is provided within handle **106** to retain plunger assembly **152** such that plunger assembly **152** is permitted to engage with suture cartridge **102**, and to translate in both the distal and proximal directions. Suitable structure for retaining plunger assembly **152** within handle **106** include, for example, a pin and shackle arrangement, a retaining collar, a boss within a groove, and the like. As depicted in FIGS. **9** and **11**, a pin and retaining shackle arrangement is employed, with the pin biased against spring **158** within slot **132** of plunger shaft **156**, in order to permit translational movement of plunger assembly **152**. Release button **160** is located on the bottom surface of handle **106**, as depicted in FIG. **10**. Release button **160** transfers an operator's input to the retaining structure of handle interface **174** in order to uncouple suture cartridge **102** from plunger assembly **152**. A track may also be provided on the top surface of handle **106** that accepts needle carriage **144**. Markings are provided on the top surface of the handle, adjacent to the track, to aid an operator in positioning needle carriage **144**.

As depicted in FIGS. **9** and **11**, plunger assembly **152** generally includes plunger thumb handle **154**, plunger shaft **156**, suture cartridge interface **184** and spring **158**, according to certain embodiments of the invention. Plunger thumb handle **154** is formed to be grasped by the thumb of an operator and is provided on the proximal end of plunger assembly **152**. Suture cartridge interface **184** is provided on the distal end of plunger assembly **152** and is formed to engage and releasably retain suture cartridges **102**. Intermediate suture cartridge interface **184** and plunger thumb handle **154** is plunger shaft **156**. Slot **132** is located along a portion of the length of plunger shaft **156**. Spring **158** is located within slot **132** of plunger shaft **156**, and in cooperation with a pin and retaining structure within handle **106**, serves to bias plunger assembly **152** to a proximal position relative to handle **106**. As a result of the releasable retention between suture cartridge interface **184** and suture cartridges **102**, the biasing action of spring **158** is translated to suture cartridge **102**. This biasing action favors retention of clamp **114** in a closed or grasping position. Biasing of plunger **152** in this manner facilitates slow and incremental clamp extension and contraction.

In one embodiment, spring **158** favors retention of clamp **114** in a closed or grasping position with a force in the range of approximately zero pounds per inch of travel to twenty pounds per inch of travel. In one embodiment, spring **158** favors retention of clamp **114** in a closed or grasping position with a force of approximately five pounds per inch of travel.

As illustrated in FIG. **7**, certain embodiments of needle assembly **116** generally include needle **138**, needle handle **140**, and needle head, or needle end, **146**. Needle **138** is formed from 304 stainless steel wire or other suitable material, is generally circular in shape, and has a distal end and a proximal end. Needle end **146** is provided on the distal end of needle **138** and needle handle **140** is provided on the proximal end of needle **138**. Needle end **146** is flattened and a notch **148** is provided to create hook **150**. Notch **148** is equal to, or greater than, the diameter of suture **112**. Needle handle **140** generally includes finger tabs **142**, and needle carriage **144**. Needle carriage **144** is permitted to travel along a track that is provided within the top housing of handle **106**. Such travel permits needle **138** from moving from a starting position (needle end **146** is within upper clamp jaw **128**, as depicted in FIG. **51**) to a fully extended position (needle hook **150** within lumen **182**). Needle carriage **144** is also permitted to travel in a proximal direction along the track, such proximal travel extending to a position where needle carriage **144** disengages from the track, and needle assembly **116** is removed from the handheld device **118**. Markings provided adjacent to the track aid an operator in selecting the correct position of the needle carriage **144** in order to achieve a desired position of needle **138**. A detent is also provided to aid in locating the starting position of needle assembly **138**. Finger tabs **142** fan out from the centerline of needle assembly **116** and in so doing, act to prevent needle carriage **144** from being inadvertently displaced. In order for an operator to displace needle carriage **144**, an operator must first grasp and press finger tabs **142** together, and then needle carriage **144** can be displaced along the track. In one embodiment, a biasing member opposes the movement of needle carriage **144** to a distal position.

According to certain embodiments of the invention, fiber optic cable assembly **108** generally includes fiber optic cable **166** and strain relief **164**. Fiber optic cable **166** generally includes four (4) fiber optic bundles **136** that run from the distal surface of upper clamp jaw **128** to the leaflet capture verification (LCV) monitor **110**. The four (4) fiber optic bundles **136** are bundled together within fiber optic cable **166** and are jacketed with a medical grade PVC cover, or other suitable covering material. Strain relief **164** is provided at the interface between fiber optic cable **166** and leaflet capture verification (LCV) monitor **110** as depicted in FIG. **12**.

According to certain embodiments of the invention, fiber optic cable assembly **108** is at least two-hundred-and-twenty centimeters long. For these embodiments, in an operating room setting, LCV monitor **110** can be placed outside of the sterile field, which results in the option to package device **100** in such a manner that LCV monitor **110** need not be sterilized.

According to another embodiment, a fiber optic connector (not depicted) can be used to operably connect fiber optic cable assembly **108** to LCV monitor **110**. The use of such a connector permits the sterilization and sterile packaging of the handheld device **118** and fiber optic cable assembly **108**, while the LCV monitor **110** can be separately packaged in an unsterilized condition. In an operating room setting, handheld device **118** and fiber optic cable assembly **108** can be introduced into the sterile field, while LCV monitor **110** can be placed outside of the sterile field, within surgical line-of-sight of a TEE monitor, and the fiber optic connector used to operably connect LCV monitor **110** and fiber optic cable assembly **108**.

As depicted in FIGS. **12** and **13**, leaflet capture verification (LCV) monitor **110** generally includes power button **168**, four (4) LED displays **170**, housing **186**, circuit board **188**,

and an internal power supply **190**, according to certain embodiments of the invention. Housing **186** includes an integrated loop which is adapted to be securely clipped or hung such that the LED displays **170** of LCV monitor **110** can be placed within surgical line-of-sight of a TEE monitor. Disposed on circuit board **188** is internal power supply **190**, power button **168** and a light source, such as an LED. For other embodiments, more than one light source can be used. Circuit board **188**, internal power supply **190**, power button **168** and the light source are all operably connected in a manner familiar to those who are skilled in the art. Activation of power button **168** results in the light source being turned on/off. Four sets of fiber optic bundles **136** enter housing **186** via fiber optic cable **166** and strain relief **164**. Each fiber optic bundle **136** generally includes two fiber optic strands. For each fiber optic bundle **136**, one of the fiber optic strands is operably connected to the light source, while the other fiber optic strand is operably connected to one of the four (4) LED displays **170**. Power button **168**, the four (4) LED displays **170**, circuit board **188**, the an internal power supply **190**, and the light source(s) are all contained within housing **186**. The four (4) LED displays **170** are visible to an operator from outside of housing **186**, and power button **168** is operable from outside of housing **186**.

In operation, device **100** can be used to attach a suture within the suture target zone **194** of a valve leaflet, as depicted in FIG. **43**. To accomplish this, the device **100** may employ a visualization and verification system. The visualization and verification system integrates external transesophageal echocardiography (TEE) to visualize a valve leaflet in multiple axes and fiber optics to verify leaflet capture. In an embodiment, suture target zone **194** is generally two millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone **194** is one millimeter wide and has a centerline that is located two millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone **194** is one millimeter wide and has a centerline that is located three millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone **194** is one millimeter wide and has a centerline that is located four millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone **194** is greater than one millimeter wide and has a centerline that is located between two millimeters and five millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone **194** is less than one millimeter wide and has a centerline that is located between two millimeters and five millimeters from the leading (prolapsing) edge of the leaflet. In one embodiment, the fiber optics include a leaflet capture verification (LCV) monitor **110** and a fiber optic cable assembly **108**, as depicted in FIGS. **1**A and **12**.

Referring to FIGS. **4**E and **4**F, in an embodiment, fiber optic bundles **136** terminate at upper clamp jaw **128** in a configuration that surrounds lumen opening **135**. In another embodiment, fiber optic bundles **136** terminate at upper clamp jaw **128** in a configuration that is near lumen opening **135**. Those skilled in the art will realize that many variations in the configuration of the placement of the terminations of fiber optic bundles **136** at clamping plane **129** are possible in order to meet the spirit and scope of the present invention. The identification of certain configurations is not intended to exclude others which are not identified, but are provided as examples of possible configurations.

Fiber optic bundles **136** are operably connected through fiber optic cable assembly **108** to the leaflet capture verification (LCV) monitor **110**, according to certain embodiments of the invention. When a valve leaflet has been grasped in clamp **114**, the LCV monitor **110** displays a light transmission that corresponds to the configuration of fiber optic bundles **136** at clamping plane **129**, and which identifies whether the valve leaflet is properly captured in clamp **114**.

According to certain embodiments, the present invention can be used with robotic multi-axis control and manipulation of the device. Proximal control of the instrument can be achieved with a system interface comprised of the necessary electrical and electro-mechanical interconnects to actuate the mechanical operations of the instrument. According to an embodiment, the distal tip of the device can have a rigid shaft. According to another embodiment, the distal end of the device can have an articulating, multiple axis tip for orientation of the clamp and suture delivery.

According to certain embodiments of the invention, the movable tip typically remains in the closed position during thoracoscopic insertion and manipulation of the handheld device **118**. As desired by an operator, plunger **152** can be manipulated to separate the two portions of the moveable tip, as depicted in, for example, FIGS. **4**D-**4**E, **4**G-**4**J and **49**.

According to certain embodiments of the invention, clamp **114** is biased to a closed position through the use of spring **158**, or other biasing member. A clamp that is biased closed aids in leaflet capture verification as it can provide a surgeon with a distinctive tactile feedback when a leaflet has been captured, as compared to when the result is a failed or partial leaflet capture.

In practice, certain embodiments of the present invention can be used to attached a suture to the suture zone of a valve leaflet in a beating heart, as depicted in FIGS. **14-42** and **46-48**. In one embodiment, the apex of the left ventricle is accessed. Such access can be obtained by thoracotomy or other suitable surgical technique. Shaft **104** of the handheld suture deployment device **118** is then inserted through the apex of the heart into the left ventricle using transesophageal echocardiography (TEE) to guide the surgeon. A purse string suture at the site of left ventricular apical access can be used to control blood loss.

As depicted in FIGS. **14-16**, while the heart is beating, the movable tip of the platform is used to guide the capture of a flailing leaflet as clamp **114** is closed. A surgeon can use external transesophageal echocardiography to guide the placement of the movable tip relative to a target leaflet. Through further use of transesophageal echocardiography, as well as the tactile feel of plunger **152**, and LCV monitor **110**, a surgeon can verify leaflet capture.

Once the leaflet is captured, a surgeon can verify capture by examining the leaflet capture verification (LCV) monitor **110** to assure leaflet tissue is present. In an embodiment, the four LED displays **170** of the LCV monitor **110** present red when blood is present at clamping plane **129**, as depicted in FIG. **17**, while a display of four white lights indicates that the tissue has been fully captured by the movable tip, as depicted in FIG. **18**.

In one embodiment, an operator can penetrate the leaflet with needle **138** and retrieve secured suture **112** from the lower clamp jaw **124** by engaging needle assembly **116**. First, needle **138** is advanced by guiding the needle assembly carriage **144** forward, or toward the distal end of the platform as depicted in FIGS. **19-24** (the movable tip is illustrated in phantom in FIGS. **21-24** so that the advancement of needle **138** can be visibly depicted). Once needle **116** is fully advanced, the needle assembly is rotated to engage suture **112** as depicted in FIGS. **25-27** (the movable tip is illustrated in phantom in FIGS. **25-27** so that the rotation of needle **138** can be visibly depicted). The suture loop is retrieved by retracting

(movement is in the proximal direction) the needle assembly entirely from handheld device **118** as depicted in FIGS. **28-32**. The handheld device **118** can then be extracted from the ventricle while maintaining control of both ends of the suture as depicted in FIGS. **33-35**.

In another embodiment, no rotation of needle **138** is necessary. A surgeon advances needle **138** by guiding the needle assembly carriage **144** forward, or toward the distal end of the platform as depicted in FIG. **8**C. Once needle **116** is fully advanced, needle hook **150** engages with suture **112**, as depicted in FIG. **8**, when needle assembly carriage **144** is retracted as depicted in FIG. **8**D. Needle hook **150** can advance past suture **112** without dislodging suture **112** from groove **162** because suture retention system **130** acts to retain suture **112** as threaded on and within suture cartridge **102**. Suture retention system **130** releases suture **112** once needle **138** has been is fully advanced.

In embodiments of the invention that have cutout **161**, handheld device **118** can be extracted with clamp **114** in a closed position. This is because cutout **161** permits suture **112** to be clear of clamp **144** after the suture loop is retrieved from handheld device **118**. Extracting handheld device **118** with clamp **114** in a closed position facilitates the extraction.

In one embodiment, the non-loop end of the suture **112** is passed through the loop to create a girth hitch on the leaflet as depicted in FIGS. **36-41** and **47-48**. The girth hitch provides for distributed stress on the leaflet with two suture legs and avoids the need for a knot at the site of leaflet capture.

In one embodiment, a surgeon can thread one of the free ends of the suture **112** into an operating-room loaded cartridge **122** and repeat the capture process on an adjacent (non-flailing) leaflet to create leaflet plication or what is commonly known as the Alfieri stitch.

In other embodiments, the handheld device **118** can be adapted to form different types of knots or stitches that can be used for mitral valve repair. This can be accomplished through changes to one or more of: the relative location of the needle within the shaft; the relative orientation of the suture within the distal tip; the configuration of the suture within the distal tip; the relative orientation of the needle hook; the addition of one or more needle ends to the needle assembly; and the relative locations of multiple needle ends within the shaft.

At this stage, the surgeon can visualize the function of the mitral valve leaflet using TEE as depicted in FIG. **42**. An operator can then incrementally adjust the tension on the suture, while monitoring the corresponding mitral valve regurgitation through the use of TEE, to allow for ideal coaptation of the mitral valve leaflets and consequently a reduction or elimination of MR. If the competency of the mitral valve is satisfactory, the suture can be secured to a suitable location. Suitable locations for this purpose can include the epicardium, a papillary muscle and other like locations. Securing the suture can be accomplished using a standard surgical knot and pledget.

In one embodiment of the present invention, the process can be repeated by removing exchangeable cartridge **102** from the handheld device **118** and replacing it with a preloaded suture cartridge **120**. In another embodiment, the process can be repeated by removing exchangeable cartridge **102** from the handheld device **118** and threading a suture **112** into operating room loaded cartridge **122** which can then be installed into handheld device **118**.

The invention claimed is:

1. A valve repair device with a replaceable suture cartridge for repair of a valve leaflet in a beating heart of a patient, comprising:

a valve repair device including a main shaft with a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient, a handle with an actuator operably connected to the proximal end of the main shaft, a capture assembly operably coupled to the distal end of the main shaft including a first portion of a jaw assembly adapted to grasp the valve leaflet in response to selective actuation of the actuator, and a needle head slidably positionable within the capture assembly to penetrate the valve leaflet and draw a suture through the valve leaflet, the main shaft further including an outwardly exposed cartridge channel extending longitudinally along substantially all of a length of the main shaft on an outwardly facing surface of the main shaft; and

a replaceable suture cartridge including a secondary shaft having a distal portion including a second portion of the jaw assembly integrally couplable to the capture assembly and a proximal end releasably couplable to the handle and the actuator, the secondary shaft being adapted to be slidingly engaged by a substantial portion of the length of the cartridge channel along a substantial portion of a length of the secondary shaft such that the main shaft and secondary shaft can be longitudinally displaced with respect to each other by sliding the secondary shaft along the cartridge channel and the actuator is actuatable to selectively position the second portion of the jaw assembly along a longitudinal axis of the capture assembly, the replaceable suture cartridge including a suture channel extending longitudinally along an exterior surface of the secondary shaft within which the suture is carried such that the suture extends out of the replaceable suture cartridge adjacent a proximal end of the secondary shaft, the main shaft at least partially covering the suture channel when the secondary shaft is slidingly engaged with the cartridge channel, and the suture having a loop portion presented proximate the jaw assembly when the replaceable suture cartridge is engaged with the valve repair device.

2. The valve repair device of claim **1**, wherein the replaceable suture cartridge further comprises a means for retaining the suture.

3. The valve repair device of claim **1**, wherein the secondary shaft defines a proximally located suture channel adapted to receive the suture, the replaceable suture cartridge further comprising a biasing member adapted to forceably retain a portion of the suture within the suture channel.

4. The valve repair device of claim **3**, wherein the needle head is slidably positionable within the capture assembly to engage the suture at a fully extended position, the biasing member being adapted to release the suture when the needle head reaches the fully extended position.

5. The valve repair device of claim **1**, wherein the handle includes a release button, and wherein the replaceable suture cartridge is configured such that actuation of the release button causes the secondary shaft to disengage from the handle.

6. The valve repair device of claim **1**, wherein the loop portion of the suture is adapted for the formation of a girth knot.

7. The valve repair device of claim **1**, wherein the loop portion of the suture is adapted for the formation of an Alfieri stitch.

8. The valve repair device of claim **1**, wherein the distal portion of the secondary shaft includes a first channel adapted to receive the loop portion and a second channel adapted to receive the needle head when actuated to an extended posi-

tion, the second channel interfacing with the first channel to present the loop portion to the needle head in the extended position.

9. The valve repair device of claim **1** wherein a plurality of the replaceable suture cartridges and the valve repair device are provided together as a kit.

10. The valve repair device of claim **1**, wherein the cartridge channel of the main shaft is keyed to slidingly receive the secondary shaft of the replaceable suture cartridge.

11. The valve repair device of claim **10**, wherein the cartridge channel is keyed such that when the secondary shaft is slidingly received in the cartridge channel the secondary shaft and main shaft can only be longitudinally moved relative to each other.

12. The valve repair device of claim **1**, wherein the proximal end of the replaceable suture cartridge includes a handle interface configured to mate with a suture cartridge interface of the handle of the valve repair device to releasably couple the proximal end of the replaceable suture cartridge to the handle.

13. The valve repair device of claim **12**, wherein a cavity of the handle interface is configured to mate with a catch mechanism on the suture cartridge interface.

14. The valve repair device of claim **13**, wherein operation of a release button releases the cavity of the handle interface from the catch mechanism on the suture cartridge interface.

15. The valve repair device of claim **12**, wherein the handle interface is retained within the handle.

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